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QIAstat-Dx® Viral Vesicular Panel Instructions for Use

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Version 2
For Research Use Only
For use with QIAstat-Dx Analyzer

REF   691731

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R1

Sample to Insight

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Intended Use

For research use only. The performance characteristics of this product have not been established. It is not for use in diagnostic procedures.

The QIAstat-Dx Viral Vesicular Panel is used to detect viral nucleic acid from transport media by real-time RT-PCR. The following pathogens can be detected and differentiated by the kit: Monkeypox virus Clade I (MPOX Clade I), Monkeypox virus Clade II (MPOX Clade II), Orthopox virus (OPXV) species, Herpes Simplex Virus 1 (HSV1), Herpes Simplex Virus 2 (HSV2), Human Herpesvirus 6 (HHV6), Human Enterovirus (HEV), and Varicella-Zoster Virus (VZV)

The assay is designed for use with the QIAstat-Dx Analyzer 1.0 or higher for integrated nucleic acid extraction and multiplex real-time RT-PCR detection.

Summary and Explanation

QIAstat-Dx Viral Vesicular Panel Cartridge Description

The QIAstat-Dx Viral Vesicular Panel cartridge is a disposable plastic device that allows performance of fully automated molecular assays for identification and differentiation of viral vesicular pathogens. The main features of the QIAstat-Dx Viral Vesicular Cartridge include compatibility with transport medium liquid samples, hermetic containment of the pre-loaded reagents necessary for testing, and true walk-away operation. All sample preparation and assay testing steps are performed within the cartridge.

All reagents required for the complete execution of a test run are pre-loaded and self-contained in the QIAstat-Dx Viral Vesicular Panel Cartridge. The user does not need to come in contact with and/or manipulate any reagents. During the test, reagents are handled within the cartridge in the Analytical Module of the QIAstat-Dx Analyzer by pneumatically-operated microfluidics, and make no direct contact with the actuators. The QIAstat-Dx Analyzer houses air filters for both incoming and outgoing air, further safeguarding the environment. After testing, the cartridge stays hermetically closed at all times, greatly enhancing its safe disposal.

Within the cartridge, multiple steps are automatically performed in sequence using pneumatic pressure to transfer samples and fluids via the transfer chamber to their intended destinations.

After the QIAstat-Dx Viral Vesicular Panel Cartridge containing the sample is introduced into the QIAstat-Dx Analyzer, the following assay steps occur automatically:

- Resuspension of the Internal Control

- Cell lysis using mechanical and/or chemical means

- Membrane-based nucleic acid purification

- Mixing of the purified nucleic acid with lyophilized master mix reagents

- Transfer of defined aliquots of eluate/master mix to different reaction chambers

- Performance of multiplex real-time RT-PCR testing within each reaction chamber

Note: An increase in fluorescence, indicating detection of the target analyte, is detected directly within each reaction chamber.
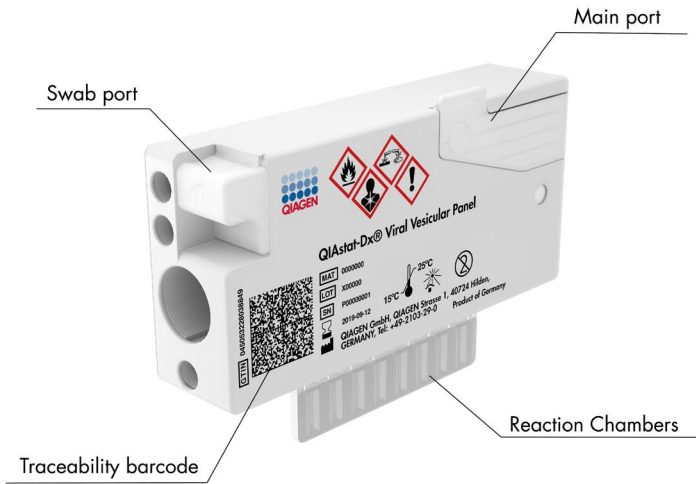

Figure 1. Layout of the QIAstat-Dx Viral Vesicular Panel Cartridge and its features.

Pathogen Information

The QIAstat-Dx Viral Vesicular Panel Cartridge is a single-use cartridge that includes all reagents needed for nucleic acid extraction, nucleic acid amplification, and detection of 6 viruses (or their strains), including MPOX Clade I and Clade II* as well as a generic Orthopoxvirus Assay. The MPOX Clade Ib, responsible for the 2024 outbreak, is detected via the generic OPXV assay. The initial version of the product showed a cross reactivity of the Clade II assay to MPOX Clade I, this was corrected in this Version 2 by the associated Assay Definition File. Testing requires a small sample volume and minimal hands-on time, and the results are available in approximately one hour.

Pathogens (and strains) that can be detected and identified with the QIAstat-Dx Viral Vesicular Panel Cartridge are listed in Table 1.

Table 1. Pathogens detected by the QIAstat-Dx Viral Vesicular Panel Cartridge

Pathogen	Classification (genome type)
Monkeypox (MPXV) Clade 1	Orthopoxvirus (linear double-stranded DNA genome)
Monkeypox (MPXV) Clade 2	Orthopoxvirus (linear double-stranded DNA genome)
Orthopox virus (OPXV) species (generic detection)	Orthopoxvirus (linear double-stranded DNA genome)
Herpes Simplex Virus 1 (HSV1)	Simplexvirus (linear double-stranded DNA genome)
Herpes Simplex Virus 2 (HSV2)	Simplexvirus (linear double-stranded DNA genome)
Human Herpes Virus 6 (HHV6)	Roseolovirus (linear double-stranded DNA genome)
Human Enterovirus (HEV)	Enterovirus (Linear single-stranded RNA genome)
Varicella-Zoster Virus(VZV)	Varicellovirus (linear double-stranded DNA genome)

*Congo Basin (CB) = Clade I, West Africa (WA) = Clade II

Principle of the Procedure

Description of the process

Samples that are tested with the QIAstat-Dx Viral Vesicular Panel are analyzed using the QIAstat-Dx Analyzer. All the sample preparation and analysis steps are performed automatically by the QIAstat-Dx Analyzer. Samples are collected and loaded manually into the QIAstat-Dx Viral Vesicular Panel Cartridge:

A transfer pipette is used for dispensing transport medium liquid sample into the main port (Figure 2).
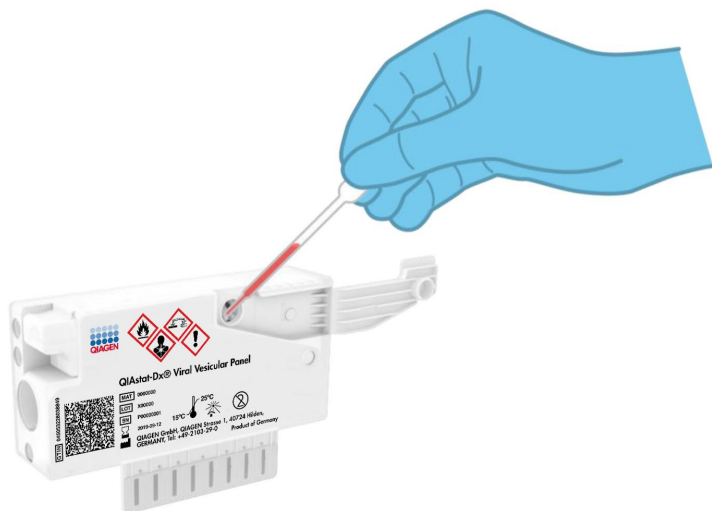

Figure 2. Dispensing transport medium liquid sample into the main port.

Sample collection and cartridge loading

The collection of samples and their subsequent loading into the QIAstat-Dx Viral Vesicular Panel Cartridge should be performed by personnel trained in safe handling of biological samples.

The following steps are involved and must be executed by the user:

1. Sample is loaded manually into the QIAstat-Dx Viral Vesicular Panel Cartridge:

   ○ **Transport medium liquid sample type**: 300 μL of sample is transferred into the main port of the using QIAstat-Dx Viral Vesicular Panel Cartridge using the included transfer pipettes.

IMPORTANT: When loading transport medium liquid sample, the user performs a visual check if the sample inspection window (see Figure 3) to confirm that the liquid sample has been loaded.
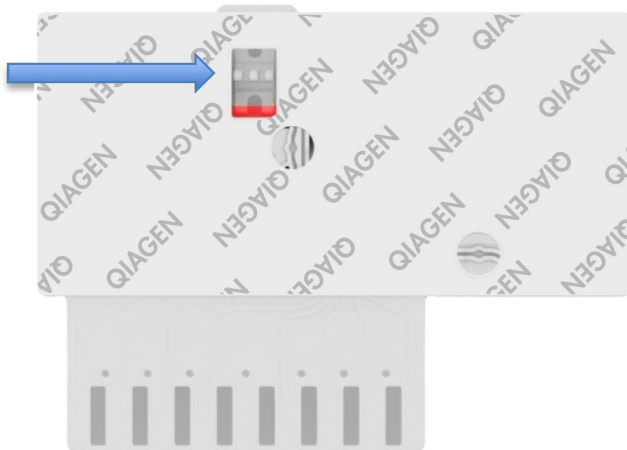

Figure 3. Sample inspection window (blue arrow).

2. The sample bar code and QIAstat-Dx Viral Vesicular Panel Cartridge bar code are scanned in the QIAstat-Dx Analyzer.

3. The QIAstat-Dx Viral Vesicular Panel Cartridge is introduced into the QIAstat-Dx Analyzer.

4. The test is started on the QIAstat-Dx Analyzer.

Sample preparation, nucleic acid amplification and detection

The extraction, amplification, and detection of nucleic acids in the sample are performed automatically by the QIAstat-Dx Analyzer.

1. The liquid sample is homogenized and virions are lysed in the lysis chamber of the QIAstat-Dx Viral Vesicular Panel Cartridge, which includes a rotor that turns at high speed.

2. Nucleic acids are purified from the lysed sample by binding to a silica membrane in the purification chamber of the QIAstat-Dx Viral Vesicular Panel Cartridge in the presence of chaotropic salts and alcohol.

3. The purified nucleic acids are eluted from the membrane in the purification chamber and are mixed with the lyophilized PCR chemistry in the dried-chemistry chamber of the QIAstat-Dx Viral Vesicular Panel Cartridge.

4. The mixture of sample and PCR reagents is dispensed into the QIAstat-Dx Viral Vesicular Panel Cartridge PCR chambers, which contain lyophilized, assay-specific primers and probes.

5. The QIAstat-Dx Analyzer creates the optimal temperature profiles to carry out effective multiplex real-time RT-PCR and performs real-time fluorescence measurements to generate amplification curves.

6. The QIAstat-Dx Analyzer Software interprets the resulting data and process controls and delivers a test report.

Materials Provided

Kit contents

QIAstat-Dx Viral Vesicular Panel	
Catalog no.	**691731**
Number of tests	**6**
QIAstat-Dx Viral Vesicular Panel Cartridge*	6
Transfer pipettes†	6

* 6 individually packaged cartridges containing all reagents needed for sample preparation and multiplex real-time RT-PCR, plus Internal Control.

† 6 individually packaged transfer pipettes for dispensing liquid sample into the QIAstat-Dx Viral Vesicular Panel Cartridge.

Materials Required but not Provided

The QIAstat-Dx Viral Vesicular Panel is designed for use with the QIAstat-Dx Analyzer . Before beginning a test, make sure the following are available:

- QIAstat-Dx Analyzer (at least 1 Operational Module and one Analytical Module) with software version 1.4 or higher[*]
- *QIAstat-Dx Analyzer 1.0 or 2.0 User Manual*
- QIAstat-Dx latest Assay Definition File software for Viral Vesicular Panel installed on the Operational Module.
  Important: The QIAstat-Dx Viral Vesicular Panel Version 2 will not run with an ADF version lower than **ADF_VV_04536_V2_0_DEV**

[*]DiagCORE® Analyzer instruments running QIAstat-Dx software version 1.4 or higher can be used as an alternative to QIAstat-Dx Analyzer instruments.

Warnings and Precautions

For Research Use Only.

The QIAstat-Dx Viral Vesicular Panel is to be used by laboratory professionals trained in the use of QIAstat-Dx Analyzer.

Safety information

When working with chemicals, always wear a suitable lab coat, disposable gloves, and protective goggles. For more information, 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.

Always wear appropriate personal protective equipment, including but not limited to disposable powder-free gloves, a lab coat, and protective eyewear. Protect skin, eyes, and mucus membranes. Change gloves often when handling samples.

Handle all samples, used cartridges and transfer pipettes as if they are capable of transmitting infectious agents. Always observe safety precautions as outlined in relevant guidelines, such as the Clinical and Laboratory Standards Institute® (CLSI) *Protection of Laboratory Workers from Occupationally Acquired Infections; Approved Guideline (M29)*, or other appropriate documents provided by the following:

- OSHA®: Occupational Safety and Health Administration (United States of America)

- ACGIH®: American Conference of Government Industrial Hygienists (United States of America)

- COSHH: Control of Substances Hazardous to Health (United Kingdom)

Follow your institution's safety procedures for handling biological samples. Dispose of samples, QIAstat-Dx Viral Vesicular Panel Cartridges, and transfer pipettes according to the appropriate regulations.

The QIAstat-Dx Viral Vesicular Panel Cartridge is a closed, single-use device that contains all reagents needed for sample preparation and multiplex real-time RT-PCR within the QIAstat-Dx Analyzer. Do not use a QIAstat-Dx Viral Vesicular Panel Cartridge that is past its expiration date, appears damaged, or leaks fluid. Dispose of used or damaged cartridges in accordance with all national, state, and local health and safety regulations and laws.

Observe standard laboratory procedures for keeping the working area clean and contamination- free. Guidelines are outlined in publications such as the *Biosafety in Microbiological and Biomedical Laboratories* from the Centers for Disease Control and Prevention and the National Institutes of Health (**www.cdc.gov/od/ohs/biosfty/biosfty.htm**).

The following hazard and precautionary statements apply to components of the QIAstat-Dx Viral Vesicular Panel Cartridge.

QIAstat-Dx Viral Vesicular Panel Cartridge

Contains: ethanol; guanidine hydrochloride; guanidine thiocyanate; isopropanol; proteinase K; t-Octylphenoxypolyethoxyethanol. Danger! Highly flammable liquid and vapour. Harmful if swallowed or if inhaled. May be harmful in contact with skin. Causes severe skin burns and eye damage. May cause allergy or asthma symptoms or breathing difficulties if inhaled. May cause drowsiness or dizziness. Harmful to aquatic life with long lasting effects. Contact with acids liberates very toxic gas. Corrosive to the respiratory tract. Keep away from heat/sparks/open flames/hot surfaces. No smoking. Avoid breathing dust/-fume/gas/mist/vapours/spray. Wear protective gloves/protective clothing/eye protection/face protection. Wear respiratory protection. IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. IF exposed or concerned: Immediately call a POISON CENTER or doctor/ physician. Remove person to fresh air and keep comfortable for breathing.

Reagent Storage and Handling

Store the QIAstat-Dx Viral Vesicular Panel Cartridges in a dry, clean storage space at room temperature (15–25°C). Do not remove the QIAstat-Dx Viral Vesicular Panel Cartridges or the transfer pipettes from their individual packaging until actual use. Under these conditions, QIAstat-Dx Viral Vesicular Panel Cartridges can be stored until the expiration date printed on the individual packaging. The expiration date is also included in the QIAstat-Dx Viral Vesicular Panel Cartridge bar code and is read by the QIAstat-Dx Analyzer when the cartridge is inserted into the instrument to run a test.

Procedure

Internal Control

The QIAstat-Dx Viral Vesicular Panel Cartridge includes a full process Internal Control, which is titered MS2 bacteriophage. The MS2 bacteriophage is a single-stranded RNA virus that is included in the cartridge in dried form and is rehydrated upon sample loading. This Internal Control material verifies all steps of the analysis process, including sample resuspension/homogenization, lysis, nucleic acid purification, reverse transcription, and PCR.

A positive signal for the Internal Control indicates that all processing steps performed by the QIAstat-Dx Viral Vesicular Panel Cartridge were successful.

A negative signal of the Internal Control does not negate any positive results for detected and identified targets, but it does invalidate all negative results in the analysis. Therefore, the test should be repeated if the Internal Control signal is negative.

Protocol: Transport Medium Liquid Samples

Loading a sample into the QIAstat-Dx Viral Vesicular Panel Cartridge

1. Open the package of a QIAstat-Dx Viral Vesicular Panel Cartridge using the tear notches on the sides of the packaging (Figure 4).

   Important: After the package is open, sample should be introduced inside the QIAstat-Dx Viral Vesicular Panel Cartridge and loaded into the QIAstat-Dx Analyzer within 120 minutes.

Figure 4. Opening the QIAstat-Dx Viral Vesicular Panel Cartridge.

2. Remove the QIAstat-Dx Viral Vesicular Panel Cartridge from the packaging and position it so that the bar code on the label faces you.

3. Manually write the sample information, or place a sample information label, on the top of the QIAstat-Dx Viral Vesicular Panel Cartridge. Make sure that the label is properly positioned and does not block the lid opening (Figure 5).

Figure 5. Sample information placement on top of QIAstat-Dx Viral Vesicular Panel Cartridge.

4. Open the sample lid of the main port on the front of the QIAstat-Dx Viral Vesicular Panel Cartridge (Figure 6).
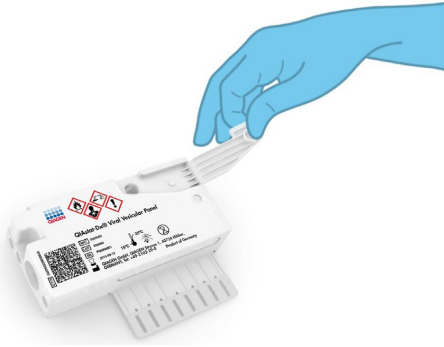
Figure 6. Opening the sample lid of main port.

5. Open the tube with the sample to be tested. Use the supplied transfer pipette to draw up fluid to the third fill line on the pipette (i.e., 300 µL) (Figure 7).

Important: Take care to avoid drawing air into the pipette.
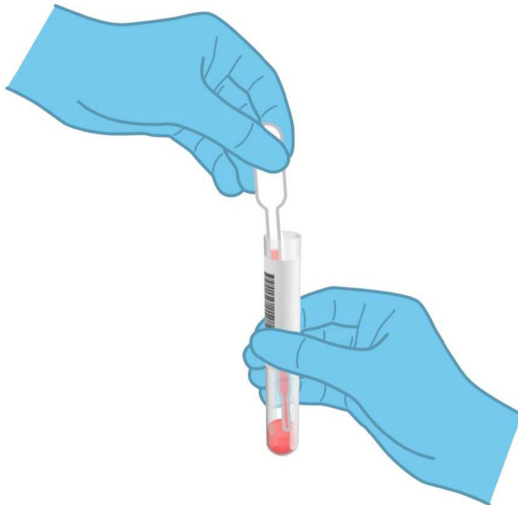
Figure 7. Drawing up sample into the supplied transfer pipette.

6. Carefully transfer 300 μL of sample volume into the main port of the QIAstat-Dx Viral Vesicular Panel Cartridge using the supplied single-use transfer pipette (Figure 8).
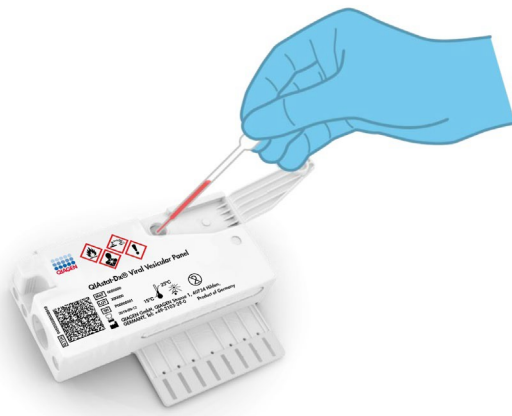
Figure 8. Transferring sample to main port of QIAstat-Dx Viral Vesicular Panel Cartridge.

7. Firmly close the sample lid of the main port until it clicks (Figure 9).

Figure 9. Closing the sample lid of the main port.

8. Visually confirm that the sample has been loaded by checking the sample inspection window of the QIAstat-Dx Viral Vesicular Panel Cartridge (Figure 10).

Important: After the sample is placed inside the QIAstat-Dx Viral Vesicular Panel Cartridge, the cartridge must be loaded into the QIAstat-Dx Analyzer within 90 minutes.
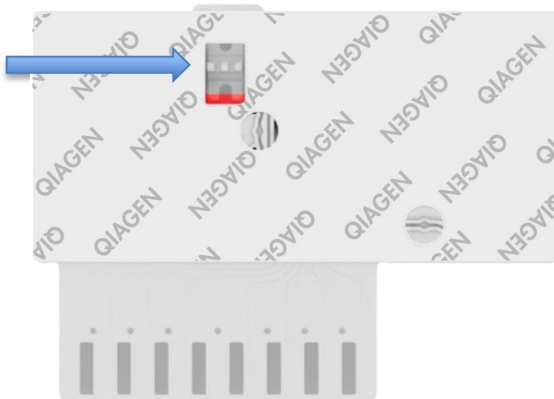
Figure 10. Sample inspection window (blue arrow).

Starting the QIAstat-Dx Analyzer

9. Power ON the QIAstat-Dx Analyzer using the **On/Off** button on the front of the instrument.

   Note: The power switch on the back of the Analytical Module must be set in the "I" position. The QIAstat-Dx Analyzer status indicators will turn blue.

10. Wait until the Main screen appears and the QIAstat-Dx Analyzer status indicators turn green and stop blinking.

11. Log in to the QIAstat-Dx Analyzer by entering the username and password.

Note: The Login screen will appear if User Access Control is activated. If the User Access Control is disabled, no username or password will be required and the Main screen will appear.

12. If the Assay Definition File software has not been installed on the QIAstat-Dx Analyzer, follow the installation instructions prior to running the test (see Appendix A: Installing the Assay Definition File, page 41, for additional information).

Running a test

13. Press the **Run Test** button in the top right corner of the touchscreen of the QIAstat-Dx Analyzer.

14. When prompted, scan the sample ID bar code on the Transport media tube containing the sample, or scan the specimen information bar code located on the top of the QIAstat-Dx Viral Vesicular Panel Cartridge (see step 3), using the integrated front bar code reader of the QIAstat-Dx Analyzer (Figure 11).

    Note: It is also possible to enter the sample ID using the virtual keyboard of the touchscreen by selecting the **Sample ID** field.

    Note: Instructions from the QIAstat-Dx Analyzer appear in the Instructions Bar at the bottom of the touchscreen.

Figure 11. Scanning sample ID bar code.

15. When prompted, scan the bar code of the QIAstat-Dx Viral Vesicular Panel Cartridge to be used (Figure 12). The QIAstat-Dx Analyzer automatically recognizes the assay to be run based on the cartridge bar code.

   Note: The QIAstat‑Dx Analyzer will not accept QIAstat‑Dx Viral Vesicular Panel Cartridges with lapsed expiration dates, previously used cartridges, or cartridges for assays that have not been installed on the unit. An error message will be shown in these cases and the QIAstat-Dx Viral Vesicular Panel Cartridge will be rejected. Refer to the *QIAstat-Dx 1.0 or 2.0 Analyzer User Manual* for further details on how to install assays.

Figure 12. Scanning QIAstat-Dx Viral Vesicular Panel Cartridge bar code.

16. The Confirm screen will appear. Review the entered data and make any necessary changes by selecting the relevant fields on the touchscreen and editing the information.

17. Press **Confirm** when all the displayed data are correct. If needed, select the appropriate field to edit its content, or press **Cancel** to cancel the test (Figure 13).
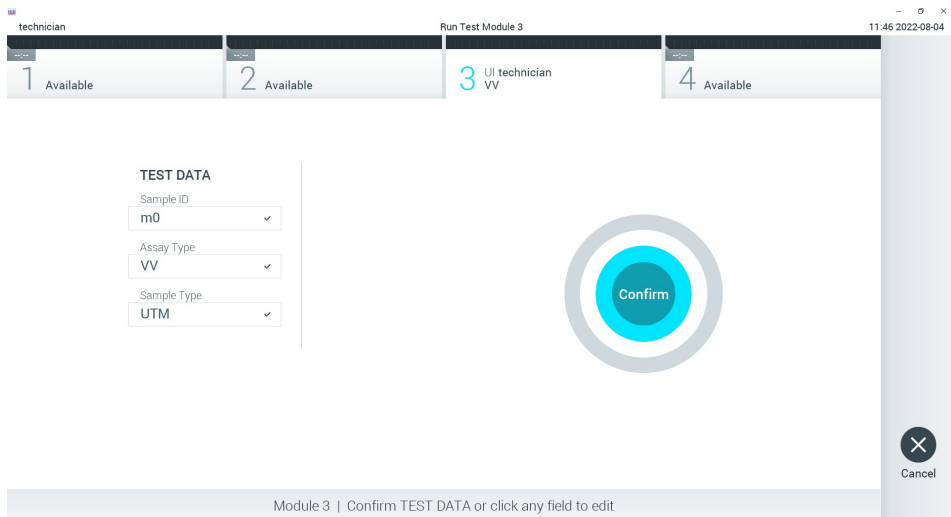
Figure 13. Confirming data entry.

18. Make sure that both sample lids of the swab port and main port of the QIAstat-Dx Viral Vesicular Panel Cartridge are firmly closed. When the cartridge entrance port on the top of the QIAstat-Dx Analyzer automatically opens, insert the QIAstat-Dx Viral Vesicular Panel Cartridge with the bar code facing to the left and the reaction chambers facing down (Figure 14).

Note: There is no need to push the QIAstat-Dx Viral Vesicular Panel Cartridge into the QIAstat-Dx Analyzer. Position it correctly into the cartridge entrance port and the QIAstat-Dx Analyzer will automatically move the cartridge into the Analytical Module.

Figure 14. Inserting QIAstat-Dx Viral Vesicular Panel Cartridge into QIAstat-Dx Analyzer.

19. Upon detecting the QIAstat-Dx Viral Vesicular Panel Cartridge, the QIAstat-Dx Analyzer will automatically close the lid of the cartridge entrance port and start the test run. No further action from the operator is required to start the run.

    Note: The QIAstat-Dx Analyzer will not accept a QIAstat-Dx Viral Vesicular Panel Cartridge other than the one used and scanned during the test setup. If a cartridge other than the one scanned is inserted, an error will be generated and the cartridge will be automatically ejected.

    Note: Up to this point, it is possible to cancel the test run by pressing the **Cancel** button in the bottom right corner of the touchscreen.

    Note: Depending on the system configuration, the operator may be required to re-enter their user password to start the test run.

Note: The lid of the cartridge entrance port will close automatically after 30 seconds if a QIAstat-Dx Viral Vesicular Panel Cartridge is not positioned in the port. If this occurs, repeat the procedure starting with step 16.

20. While the test is running, the remaining run time is displayed on the touchscreen.

21. After the test run is completed, the Eject screen will appear (Figure 15) and the Module status bar will display the test result as one of the following options:

   ○ **TEST COMPLETED**: The test was completed successfully

   ○ **TEST FAILED**: An error occurred during the test

   ○ **TEST CANCELED**: The user canceled the test

   Important: If the test fails, refer to the "Troubleshooting" section in the *QIAstat-Dx Analyzer 1.0 or 2.0 User Manual* for possible reasons and instructions on how to proceed.
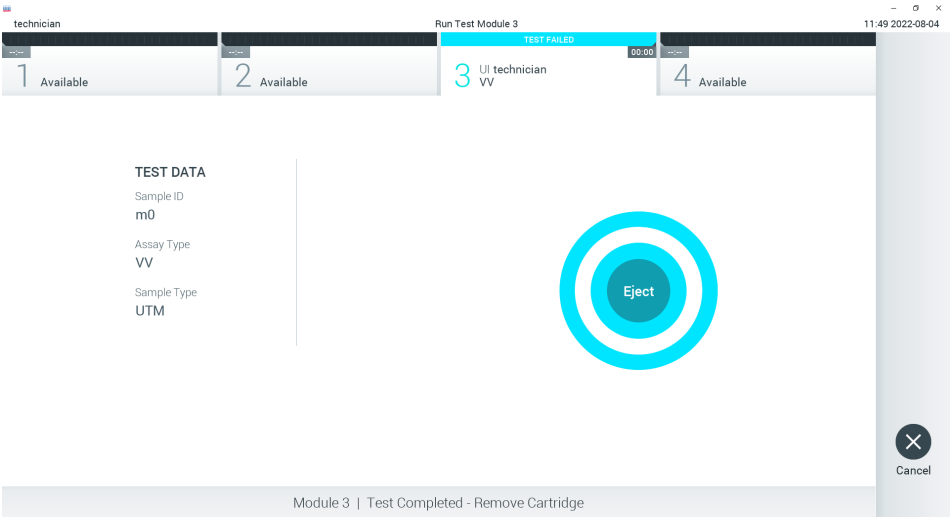
Figure 15. Eject screen display.

22. Press ⊙ **Eject** on the touchscreen to remove the QIAstat-Dx Viral Vesicular Panel Cartridge and dispose of it as biohazardous waste in accordance with all national, state and local health and safety regulations and laws. The QIAstat-Dx Viral Vesicular Panel Cartridge should be removed when the cartridge entrance port opens and ejects the cartridge. If the cartridge is not removed after 30 seconds, it will automatically move back into the QIAstat-Dx Analyzer and cartridge entrance port lid will close. If this occurs, press **Eject** to open the lid of the cartridge entrance port again and then remove the cartridge

    Important: Used QIAstat-Dx Viral Vesicular Panel Cartridges must be discarded. It is not possible to re-use cartridges for tests for which the execution was started but then subsequently canceled by the operator, or for which an error was detected.

23. After the QIAstat-Dx Viral Vesicular Panel Cartridge has been ejected, the results Summary screen will appear. Refer to "Interpretation of Results" for further details. To begin the process for running another test, press **Run Test**.

    Note: For further information on the use of the QIAstat-Dx Analyzer, refer to the *QIAstat-Dx Analyzer 1.0 or 2.0 User Manual.*

Interpretation of Results

Viewing results

The QIAstat-Dx Analyzer automatically interprets and saves test results. After ejecting the QIAstat-Dx Viral Vesicular Panel Cartridge, the results Summary screen is automatically displayed (Figure 16).
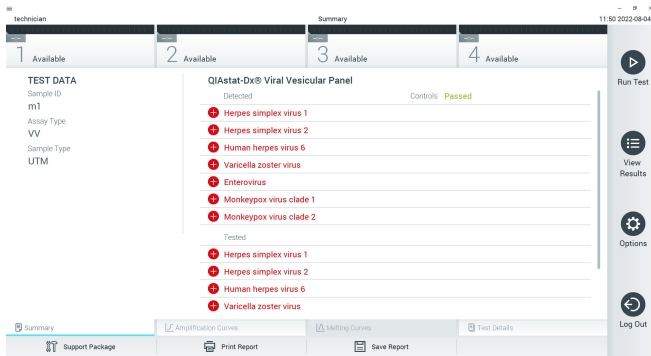

Figure 16. Results Summary screen example showing Test Data on the left panel and Test Summary in the main panel.

The main part of the screen provides the following three lists and uses color-coding and symbols to indicate the results:

- The first list, under the heading "Detected", includes all pathogens detected and identified in the sample, which are preceded by a ⊕ sign and are colored red.

- The second list, under the heading "Equivocal" is not used. "Equivocal" results are not applicable for the QIAstat-Dx Viral Vesicular Panel. Therefore, the "Equivocal" list will always be empty.

- The third list, under the heading "Tested", includes all pathogens tested in the sample. Pathogens detected and identified in the sample are preceded by a ⊕ sign and are

colored red. Pathogens that were tested but not detected are preceded by a ⊖ sign and are colored green.

Note: Pathogens detected and identified in the sample are shown in both the "Detected" and "Tested" lists.

If the test failed to complete successfully, a message will indicate "Failed" followed by the specific Error Code.

The following Test Data[*] are shown on the left side of the screen:

- Sample ID
- Assay Type
- Sample Type

Further data about the assay is available, depending on the operator's access rights, through the tabs at the bottom of the screen (e.g., amplification plots and test details).

A report with the assay data can be exported to an external USB storage device. Insert the USB storage device into one of the USB ports of the QIAstat-Dx Analyzer and press **Save Report** in the bottom bar of the screen. This report can be exported later at any time by selecting the test from the View Result List.

The report can also be sent to the printer by pressing **Print Report** in the bottom bar of the screen.

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[*]Patient ID will be shown on the screen in those OM that have this field activated in configuration menu. This field is not applicable to Viral Vesicular Panel research use only product.

Viewing amplification curves

To view test amplification curves of pathogens detected, press the [icon] Amplification Curves tab (Figure 17).

Figure 17. Amplification Curves screen (PATHOGENS tab).

Details about the tested pathogens and controls are shown on the left and the amplification curves are shown in the center.

Note: If User Access Control is enabled on the QIAstat-Dx Analyzer the Amplification Curves screen is only available for operators with access rights.

Press the **PATHOGENS** tab on the left side to display the plots corresponding to the tested pathogens. Press on the pathogen name to select which pathogens are shown in the amplification plot. It is possible to select single, multiple, or no pathogens. Each pathogen in the selected list will be assigned a color corresponding to the amplification curve associated with the pathogen. Unselected pathogens will be shown in gray.

The corresponding C_T and endpoint fluorescence (EP) values are shown below each pathogen name.

Press the **CONTROLS** tab on the left side to view the controls in the amplification plot. Press the circle next to the control name to select or deselect it (Figure 18).
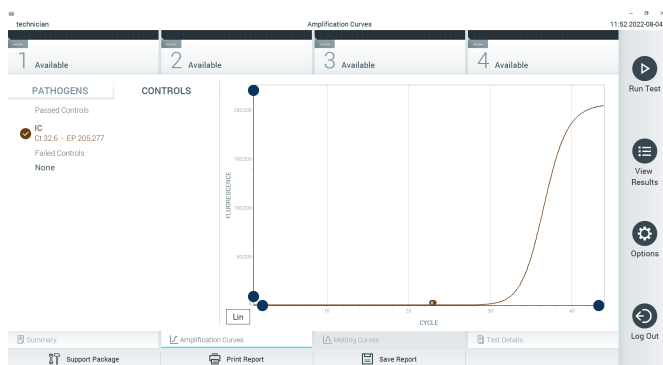

Figure 18. Amplification Curves screen (CONTROLS tab).

The amplification plot displays the data curve for the selected pathogens or controls. To alternate between logarithmic or linear scale for the Y-axis, press the **Lin** or **Log** button at the bottom left corner of the plot.

The scale of the X-axis and Y-axis can be adjusted using the ● blue pickers on each axis. Press and hold a blue picker and then move it to the desired location on the axis. Move a blue picker to the axis origin to return to the default values.

Viewing test details

Press ▤ **Test Details** in the Tab Menu bar at the bottom of the touchscreen to review the results in more detail. Scroll down to see the complete report.

The following Test Details are shown in the center of the screen (Figure 19).

- User ID

- Cartridge SN (serial number)

- Cartridge Expiration Date

- Module SN (serial number)

- Test Status (Completed, Failed or Canceled by operator)

- Error Code (if applicable)

- Test Start Date and Time

- Test Execution Time

- Assay Name

- Test ID Test Result:

    ○ pos: Positive — if there is at least one target detected or identified

    ○ neg: Negative — if there are no target detected or identified

    ○ invalid

- List of analytes tested in the assay, with C_T and endpoint fluorescence in the event of a positive signal

- Internal Control, with C_T and endpoint fluorescence
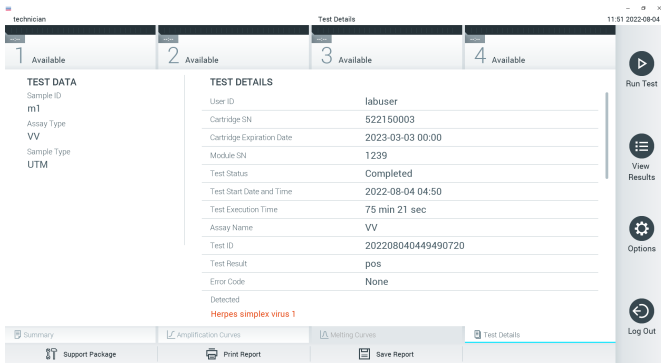
Figure 19. Example screen showing Test Data on the left panel and Test Details in the main panel.

Browsing results from previous tests

To view results from previous tests that are stored in the results repository, press 🔢 **View Results** on the Main Menu bar (Figure 20).
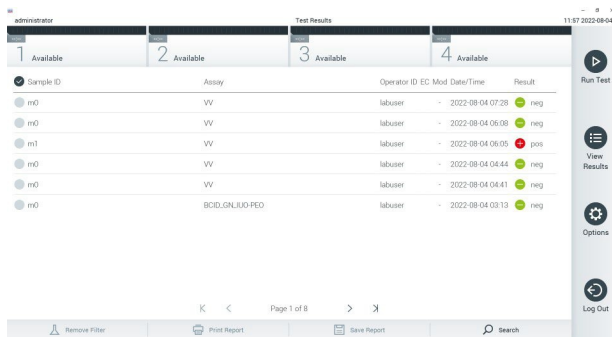
Figure 20. Example View Results screen.

The following information is available for every executed test (Figure 21):

- Sample ID

- Assay (name of test assay, which is "VV" for Viral Vesicular Panel)

- Operator ID

- Mod (Analytical Module on which the test was executed)

- Date/Time (date and time when the test was finished)

- Result (outcome of the test: positive [pos], negative [neg], failed [fail] or successful [suc])

Note: If User Access Control is enabled on the QIAstat-Dx Analyzer, the data for which the user has no access rights will be hidden with asterisks.

Select one or more test results by pressing the gray circle to left of the sample ID. A checkmark will appear next to selected results. Unselect test results by pressing this checkmark. The entire list of results can be selected by pressing the ✔ checkmark circle in the top row (Figure 21).
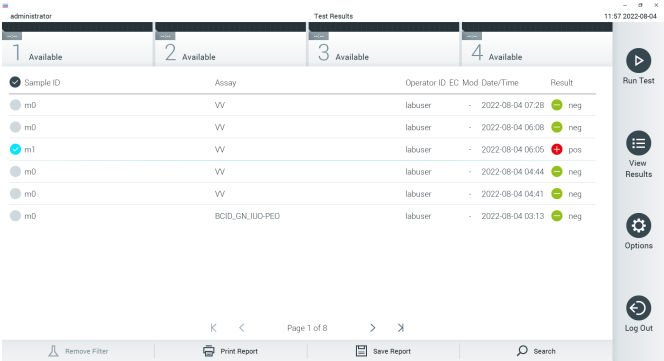
Figure 21. Example of selecting Test Results in the View Results screen.

Press anywhere in the test row to view the result for a particular test.

Press a column headline (e.g., Sample ID) to sort the list in ascending or descending order according to that parameter. The list can be sorted according to only one column at a time.

The Result column shows the outcome of each test (Table 2):

Table 2. Descriptions of test results

Outcome	Result	Description
Positive	➕ pos	At least one pathogen is positive.
Negative	➖ neg	No pathogens were detected.
Failed	✖ fail	The test failed because either an error occurred or the test was canceled by the user.
Successful	✔ suc	The test is either positive or negative, but the user does not have the access rights to view the test results.

1. Make sure a printer is connected to the QIAstat-Dx Analyzer and the proper driver is installed. Press **Print Report** to print the report(s) for the selected result(s).

2. Press **Save Report** to save the report(s) for the selected result(s) in PDF format to an external USB storage device.

3. Select the report type: **List of Tests** or **Test Reports**.

4. Press **Search** to search the test results by Sample ID, Assay and Operator ID. Enter the search string using the virtual keyboard and press **Enter** to start the search. Only the records containing the search text will be displayed in the search results.

5. If the results list has been filtered, the search will only apply to the filtered list.

6. Press and hold a column headline to apply a filter based on that parameter. For some parameters, such as Sample ID, the virtual keyboard will appear so the search string for the filter can be entered.

7. For other parameters, such as Assay, a dialog will open with a list of assays stored in the repository. Select one or more assays to filter only the tests that were performed with the selected assays.

8. The 🔲 symbol to the left of a column headline indicates that the column's filter is active.

9. A filter can be removed by pressing **Remove Filter** in the Submenu bar.

Exporting results to a USB drive

From any tab of the View Results screen, select **Save Report** to export and save a copy of the test results in PDF format to a USB drive. The USB port is located on the front of the QIAstat-Dx Analyzer.

Printing results

Make sure a printer is connected to the QIAstat-Dx Analyzer and the proper driver is installed. Press **Print Report** to send a copy of the test results to the printer.

Internal Control interpretation

Internal Control results are to be interpreted according to Table 3.

Table 3. Interpretation of Internal Control results

Control result	Explanation	Action
Passed	The Internal Control amplified successfully.	The run was completed with success. All results are validated and can be reported. Detected pathogens are reported as "positive" and undetected pathogens are reported as "negative".
Failed	The Internal Control failed.	Positively detected pathogen(s) are reported, but all negative results (tested but not detected pathogen[s]) are invalid. Repeat the testing using a new QIAstat-Dx Viral Vesicular Panel Cartridge.

Quality Control

In accordance with QIAGEN's ISO-certified Quality Management System, each lot of QIAstat-Dx Viral Vesicular Panel is tested against predetermined specifications to ensure consistent product quality.

Limitations

- Results from the QIAstat-Dx Viral Vesicular Panel are not intended to be used for diagnosis, treatment or other patient management decisions.

- Positive results do not rule out the presence of other organisms not included in the QIAstat-Dx Viral Vesicular Panel.

- A negative result with the QIAstat-Dx Viral Vesicular Panel may originate from several factors and their combinations, including sample handling mistakes, variation in the nucleic acid sequences targeted by the assay, presence of organisms not included in the assay, and organism levels of included organisms that are below the limit of detection for the assay.

- MPOX Clade Ib positive samples will not be detected by the MPOX Clade I assay in this product but will generate a positive signal for the pan OPXV assay.

- The QIAstat-Dx Viral Vesicular Panel is not intended for testing of samples other than those described in these Instructions for Use.

- The QIAstat-Dx Viral Vesicular Panel can be used only with the QIAstat-Dx Analyzer[*]

- The QIAstat-Dx Viral Vesicular Panel is a qualitative assay and does not provide a quantitative value for detected organisms.

- Detection of viral nucleic acids depends on proper sample collection, handling, transportation, storage and loading into the QIAstat-Dx Viral Vesicular Panel Cartridge. Improper operations for any of the afore mentioned processes can cause incorrect results, including false-positive or false-negative results.

[*]DiagCORE Analyzer instruments running QIAstat-Dx software version 1.4 or higher can be used as an alternative to QIAstat-Dx Analyzer instruments.

Appendix A: Installing the Assay Definition File

The Assay Definition File of the QIAstat-Dx Viral Vesicular Panel must be installed on the QIAstat-Dx Analyzer prior to testing with QIAstat-Dx Viral Vesicular Panel Cartridges.

Note: Whenever a new version of the QIAstat-Dx Viral Vesicular Panel assay is released, the new QIAstat-Dx Viral Vesicular Panel Assay Definition File must be installed prior to testing.

Note: Assay Definition Files are available at **www.qiagen.com**

The Assay Definition File (.asy file type) must be saved onto a USB Drive prior to installation on the QIAstat-Dx Analyzer. This USB Drive must be formatted with a FAT32 file system.

To import new assays from the USB to the QIAstat-Dx Analyzer, proceed with the following steps:

1. Insert the USB stick containing the Assay Definition File into one of the USB ports on the QIAstat-Dx Analyzer.

2. Press the **Options** button and then select Assay Management. The Assay Management screen appears in the Content area of the display (Figure 22).
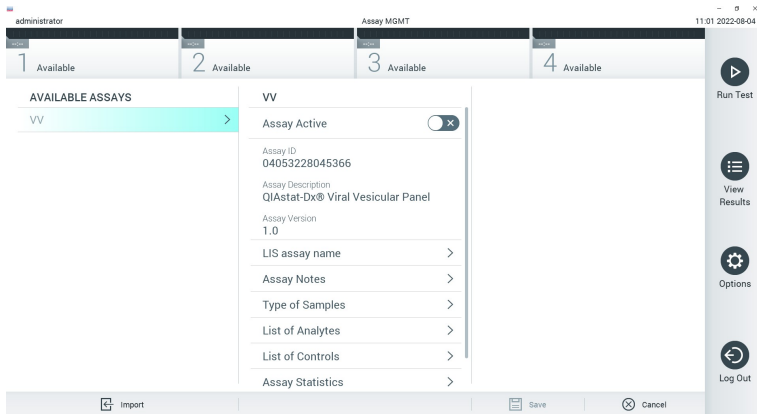
Figure 22. Assay Management screen.

3. Press the **Import** icon in the bottom left of the screen.

4. Select the file corresponding to the assay to be imported from the USB drive.

5. A dialog will appear to confirm upload of the file.

6. A dialog may appear to override the current version by a new one. Press **Yes** to override.

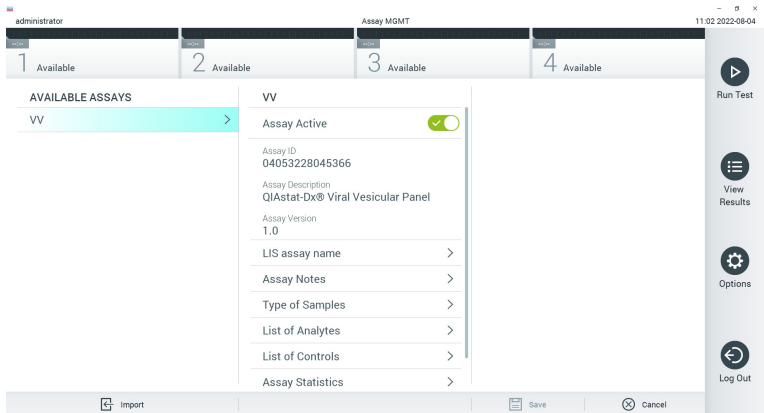7. The assay becomes active by selecting **Assay Active** (Figure 23).

Figure 23. Activating the assay.

8. Assign the active assay to the user by pressing the **Options** button and then the **User Management** button. Select the user who should be allowed to run the assay. Next, select **Assign Assays** from the "User Options". Enable the assay and press the **Save** button (Figure 24).
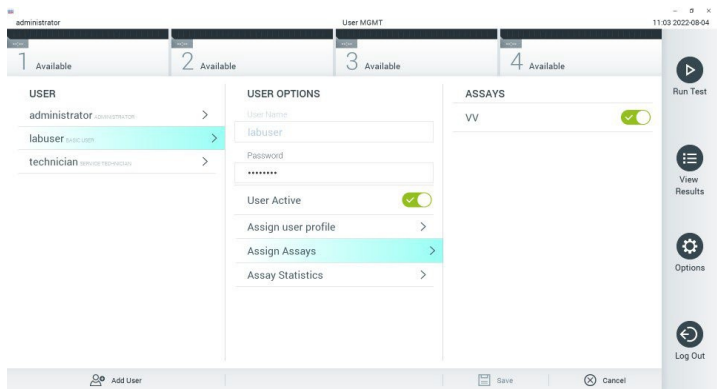

Figure 24. Assigning the active assay.

Appendix B: Glossary

- **Amplification curve**: Graphical representation of the multiplex real-time RT-PCR amplification data.

- **Analytical Module (AM)**: The main QIAstat-Dx Analyzer hardware module, in charge of executing tests on QIAstat-Dx Viral Vesicular Panel Cartridges. It is controlled by the Operational Module. Several Analytical Modules can be connected to one Operational Module.

- **IFU**: Instructions For Use.

- **Main port**: In the QIAstat-Dx Viral Vesicular Panel Cartridge, inlet for transport medium liquid samples.

- **Nucleic acids**: Biopolymers, or small biomolecules composed of nucleotides, which are monomers made of three components: a 5-carbon sugar, a phosphate group and a nitrogenous base.

- **Operational Module (OM)**: The dedicated QIAstat-Dx Analyzer hardware that provides the user interface for 1–4 Analytical Modules (AM).

- **PCR**: Polymerase Chain Reaction

- **QIAstat-Dx Analyzer**: The QIAstat-Dx Analyzer consists of an Operational Module and an Analytical Module. The Operational Module includes elements that provide connectivity to the Analytical Module and enables user interaction with the QIAstat-Dx Analyzer. The Analytical Module contains the hardware and software for sample testing and analysis.

- **QIAstat-Dx Viral Vesicular Panel Cartridge**: A self-contained disposable plastic device with all pre-loaded reagents required for the complete execution of fully automated molecular assays for the detection of nucleic acids.

- **RT**: Reverse Transcription

- **User**: A person who operates the QIAstat-Dx Analyzer /QIAstat-Dx Viral Vesicular Panel Cartridge in the intended way.

Appendix C: Disclaimer of warranties

EXCEPT AS PROVIDED IN QIAGEN TERMS AND CONDITIONS OF SALE FOR THE QIAstat-Dx Viral Vesicular Panel Cartridge, QIAGEN ASSUMES NO LIABILITY WHATSOEVER AND DISCLAIMS ANY EXPRESS OR IMPLIED WARRANTY RELATING TO THE USE OF THE QIAstat-Dx Viral Vesicular Panel Cartridge INCLUDING LIABILITY OR WARRANTIES RELATING TO MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, OR INFRINGEMENT OF ANY PATENT, COPYRIGHT, OR OTHER INTELLECTUAL PROPERTY RIGHT ANYWHERE IN THE WORLD.

References

1. Centers for Disease Control and Prevention (CDC) website: Monkeypox. https://www.cdc.gov/poxvirus/monkeypox/index.html

2. World Health Organization (WHO) website: Monkeypox.https://www.who.int/news-room/fact-sheets/detail/monkeypox

Symbols

The following table describes the symbols that may appear on the labeling or in this document.

Symbol	Symbol definition
∑ <N>	Contains reagents sufficient for <N> reactions
⧗	Use by
REF	Catalog number
LOT	Lot number
MAT	Material number (i.e., component labeling)
Rn	R is for revision of the Instructions for Use and n is the revision number
🌡	Temperature limitation
🏭	Manufacturer
📖	Consult instructions for use

Symbol	Symbol definition
⚠	Caution, consult accompanying documents
SN	Serial Number
⊘	Do not reuse
☀	Keep away from sunlight
⊘	Do not use if package is damaged
GTIN	Global Trade Item Number

Ordering Information

Product	Contents	Cat. no.
QIAstat-Dx Viral Vesicular Panel Version 2	For 6 tests: 6 individually packaged QIAstat-Dx Viral Vesicular Panel Cartridges and 6 individually packaged transfer pipettes	691731
Related Products		
QIAstat-Dx Analyzer 1.0	1 QIAstat-Dx Analytical Module, 1 QIAstat-Dx Operational Module and related hardware and software to run QIAstat-Dx assay cartridges	9002824
QIAstat-Dx Analyzer 2.0	1 QIAstat-Dx Analytical Module, 1 QIAstat-Dx Operational Module PRO and related hardware and software to run QIAstat-Dx assay cartridges	9002828

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Document Revision History

Date	Changes
R1, September 2024	Initial Release.

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