



QIAstat-Dx RP SARS-CoV-2 Control Panel

INTENDED USE:

QIAstat-Dx RP SARS-CoV-2 Control Panel is intended for use (as applicable) as an external positive and negative quality control to monitor the performance of *in vitro* laboratory nucleic acid testing procedures for the qualitative detection of bacterial and viral pathogens: Adenovirus, Bocavirus, Coronavirus 229E, Coronavirus HKU1, Coronavirus NL63, Coronavirus OC43, Severe Acute Respiratory-Coronavirus 2 (SARS-CoV-2), Human Metapneumovirus A+B, Influenza A, Influenza A H1, Influenza A H1N1 pdm09, Influenza A H3, Influenza B, Parainfluenza virus 1, Parainfluenza virus 2, Parainfluenza virus 3, Parainfluenza virus 4, Respiratory Syncytial Virus A+B, Rhinovirus/Enterovirus, *Bordetella pertussis*, *Chlamydomphila pneumoniae*, *Legionella pneumophila* and *Mycoplasma pneumoniae* using the QIAstat-Dx[®] Respiratory SARS-CoV-2 Panel, QIAstat-Dx Respiratory Panel Plus and QIAstat-Dx Respiratory Panel Mini on the QIAstat-Dx systems. QIAstat-Dx RP SARS-CoV-2 Control Panel contains synthetic RNA specifically designed for and intended to be used solely with the QIAstat-Dx Respiratory SARS-CoV-2 Panel, QIAstat-Dx Respiratory Panel Plus and QIAstat-Dx Respiratory Panel Mini.

Quality control materials should be used in accordance with local, state, and federal regulations and accreditation requirements.

PRODUCT SUMMARY and PRINCIPLE:

QIAstat-Dx RP SARS-CoV-2 Control Panel is composed of 3 controls, QIAstat-Dx RP Positive A, QIAstat-Dx RP Positive B1, and QIAstat-Dx RP Negative. QIAstat-Dx RP Positive A and QIAstat-Dx RP Positive B1 contain surrogate control material composed of synthetic nucleic acid corresponding to genome segments of pathogens listed in Tables 1, 2 and 3. QIAstat-Dx RP Negative contains no nucleic acid.

Quality controls can be used for routine monitoring of test systems, validation, verification, proficiency assessment, and training procedures. Quality controls that are consistent from lot to lot assist the laboratory in identifying shifts, trends, and increased frequency of random errors caused by variations in the test system, such as failing reagents or malfunctioning equipment. Early investigation can prevent failed assay runs.

COMPOSITION:

The QIAstat-Dx RP SARS-CoV-2 Control Panel is comprised of 12 single use tubes, 4 tubes of QIAstat-Dx RP Positive A, 4 tubes of QIAstat-Dx RP Positive B1, and 4 tubes of QIAstat-Dx RP Negative, 300µL each. QIAstat-Dx RP Positive A and QIAstat-Dx RP Positive B1 contain synthetic RNA suspended in a non-infectious solution of buffers, preservatives and stabilizers. QIAstat-Dx RP Negative contains buffers and preservatives. Tables 1, 2 and 3 list the pathogens that are detected in the QIAstat-Dx RP SARS-CoV-2 Control Panel when tested by the QIAstat-Dx Respiratory SARS-CoV-2 Panel, QIAstat-Dx Respiratory Panel Plus and QIAstat-Dx Respiratory Panel Mini on the QIAstat-Dx systems.

STORAGE and STABILITY:

QIAstat-Dx RP SARS-CoV-2 Control Panel should be stored frozen (-25°C to -15°C). Unopened QIAstat-Dx RP SARS-CoV-2 Control Panel material is stable through the expiration date printed on the kit label when consistently stored frozen. QIAstat-Dx RP Positive A, QIAstat-Dx RP Positive B1, and QIAstat-Dx RP Negative are for single use only. Discard after use according to your local and federal regulations.

PRECAUTIONS, WARNINGS, and LIMITATIONS:

- Do not dilute. Use the control as provided.
- This product is intended for *in vitro* analytical testing and is provided for Research Use Only, not for use in diagnostic procedures.
- This product is for use solely with QIAstat-Dx Respiratory SARS-CoV-2 Panel, QIAstat-Dx Respiratory Panel Plus and QIAstat-Dx Respiratory Panel Mini on the QIAstat-Dx systems. It does not contain the entire genome of the respiratory pathogens listed in Tables 1, 2 and 3.
- This product is not intended for use as a substitute for the internal controls provided in the QIAstat-Dx Respiratory SARS-CoV-2 Panel, QIAstat-Dx Respiratory Panel Plus and QIAstat-Dx Respiratory Panel Mini.
- Appearance: Positive A & B1 controls are slightly cloudy and Negative control is clear.
- This product does not contain any biological material of human or animal origin. Universal Precautions are NOT required when handling this product.
- QIAstat-Dx RP SARS-CoV-2 Control Panel cannot be cloned, sold, or transferred without the explicit written consent of MMQCI.

INSTRUCTIONS FOR USE:

1. Allow the control to be tested to come completely to room temperature (18°C – 25°C).
2. Use the control as provided. DO NOT DILUTE.
3. Prepare a QIAstat-Dx Respiratory SARS-CoV-2 Panel cartridge, QIAstat-Dx Respiratory Panel Plus cartridge or QIAstat-Dx Respiratory Panel Mini cartridge according to the QIAstat-Dx Respiratory SARS-CoV-2 Panel, QIAstat-Dx Respiratory Panel Plus or QIAstat-Dx Respiratory Panel Mini Instructions for Use.
4. Open the sample lid of the main port on the front of the QIAstat-Dx Respiratory SARS-CoV-2 Panel cartridge, QIAstat-Dx Respiratory Panel Plus cartridge or QIAstat-Dx Respiratory Panel Mini cartridge according to the QIAstat-Dx Respiratory SARS-CoV-2 Panel, QIAstat-Dx Respiratory Panel Plus or QIAstat-Dx Respiratory Panel Mini Instructions for Use.
5. Immediately before use, **mix the control thoroughly by inverting 3-5 times or pulse vortex for 3-5 seconds**, and tap the tube several times on the bench to remove any control caught in the cap before opening the tube.
6. Use the supplied transfer pipette to draw up the liquid control to the third fill line on the pipette (300µL).
7. Carefully transfer 300µL of sample volume into the main port on the QIAstat-Dx Respiratory SARS-CoV-2 Panel cartridge, QIAstat-Dx Respiratory Panel Plus cartridge or QIAstat-Dx Respiratory Panel Mini cartridge. Firmly close the sample lid of the main port until it clicks.
8. Visually confirm that the sample has been loaded by checking the sample inspection window in the cartridge.
9. The controls are single use only. Discard control tube after use according to your local and federal regulations.
10. Continue to process the control according to the assay Instructions for Use.

ORDERING INFORMATION:

QIAstat-Dx RP SARS-CoV-2 Control Panel
Part Number: M360v1.2
Kit Contains: 12 tubes x 300µL
4 each Positive A, Positive B1, and Negative



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EXPECTED VALUES:

The tables below list the expected results when QIAstat-Dx RP SARS-CoV-2 Control Panel is analyzed by QIAstat-Dx Respiratory SARS-CoV-2 Panel (Table 1), QIAstat-Dx Respiratory Panel Plus (Table 2), and QIAstat-Dx Respiratory Panel Mini (Table 3). *Note that the reported Ct/EP may vary run to run, and among different instruments and laboratories.*

The laboratory should follow Good Laboratory Practice (GLP) and establish its own performance characteristics for QIAstat-Dx RP SARS-CoV-2 Control Panel in demonstrating adequate system performance.

Table 1: Expected Results for QIAstat-Dx RP SARS-CoV-2 Control Panel Analyzed with the QIAstat-Dx Respiratory SARS-CoV-2 Panel.

Result Details			
	Positive A	Positive B1	Negative
Viruses			
Adenovirus	+ Detected	Not Detected	Not Detected
Bocavirus*	Not Detected	+ Detected	Not Detected
Coronavirus 229E	+ Detected	Not Detected	Not Detected
Coronavirus HKU1	Not Detected	+ Detected	Not Detected
Coronavirus NL63	+ Detected	Not Detected	Not Detected
Coronavirus OC43	Not Detected	+ Detected	Not Detected
Human Metapneumovirus A+B	+ Detected	Not Detected	Not Detected
Influenza A*†	+ Detected	+ Detected	Not Detected
Influenza A H1	+ Detected	Not Detected	Not Detected
Influenza A H1N1 pdm09	+ Detected	Not Detected	Not Detected
Influenza A H3	Not Detected	+ Detected	Not Detected
Influenza B	Not Detected	+ Detected	Not Detected
Parainfluenza virus 1	+ Detected	Not Detected	Not Detected
Parainfluenza virus 2	Not Detected	+ Detected	Not Detected
Parainfluenza virus 3	+ Detected	Not Detected	Not Detected
Parainfluenza virus 4	Not Detected	+ Detected	Not Detected
Respiratory Syncytial Virus A+B	Not Detected	+ Detected	Not Detected
Rhinovirus/Enterovirus	+ Detected	Not Detected	Not Detected
SARS-CoV-2	Not Detected	+ Detected	Not Detected
Bacteria			
<i>Bordetella pertussis</i>	Not Detected	+ Detected	Not Detected
<i>Chlamydomphila pneumoniae</i>	Not Detected	+ Detected	Not Detected
<i>Legionella pneumophila</i> *	+ Detected	Not Detected	Not Detected
<i>Mycoplasma pneumoniae</i>	+ Detected	Not Detected	Not Detected

* Bocavirus, Influenza A, and *Legionella pneumophila* are reported for NON-US customers only.

† Influenza A is reported in the Negative control in the US.

Table 2: Expected Results for QIAstat-Dx RP SARS-CoV-2 Control Panel Analyzed with the QIAstat-Dx Respiratory Panel Plus.

Result Details			
	Positive A	Positive B1	Negative
Viruses			
Adenovirus	+ Detected	Not Detected	Not Detected
Human Coronavirus 229E	+ Detected	Not Detected	Not Detected
Human Coronavirus HKU1	Not Detected	+ Detected	Not Detected
Human Coronavirus NL63	+ Detected	Not Detected	Not Detected
Human Coronavirus OC43	Not Detected	+ Detected	Not Detected
Human Metapneumovirus	+ Detected	Not Detected	Not Detected
Human Rhinovirus/Enterovirus	+ Detected	Not Detected	Not Detected
Influenza A‡			Not Detected
Influenza A H1	+ Detected	Not Detected	Not Detected
Influenza A H1N1 pdm09	+ Detected	Not Detected	Not Detected
Influenza A H3	Not Detected	+ Detected	Not Detected
Influenza B	Not Detected	+ Detected	Not Detected
Parainfluenza virus 1	+ Detected	Not Detected	Not Detected
Parainfluenza virus 2	Not Detected	+ Detected	Not Detected
Parainfluenza virus 3	+ Detected	Not Detected	Not Detected
Parainfluenza virus 4	Not Detected	+ Detected	Not Detected
Respiratory Syncytial Virus	Not Detected	+ Detected	Not Detected
SARS-CoV-2	Not Detected	+ Detected	Not Detected
Bacteria			
<i>Bordetella pertussis</i>	Not Detected	+ Detected	Not Detected
<i>Chlamydomphila pneumoniae</i>	Not Detected	+ Detected	Not Detected
<i>Mycoplasma pneumoniae</i>	+ Detected	Not Detected	Not Detected

‡ When a subtype of Influenza A (Influenza A H1, Influenza A H1N1 pdm09, or Influenza A H3) is detected, Influenza A will not appear on the assay report. It is expected to appear in the assay report for the Negative control as Not Detected.

Table 3: Expected Results for QIAstat-Dx RP SARS-CoV-2 Control Panel Analyzed with the QIAstat-Dx Respiratory Panel Mini.

Result Details			
	Positive A	Positive B1	Negative
Viruses			
Influenza A	+ Detected	+ Detected	Not Detected
Influenza B	Not Detected	+ Detected	Not Detected
Respiratory Syncytial Virus	Not Detected	+ Detected	Not Detected
Human Rhinovirus	+ Detected	Not Detected	Not Detected
SARS-CoV-2	Not Detected	+ Detected	Not Detected