



QIAstat-Dx RP SARS-CoV-2 Negative

INTENDED USE:

QIAstat-Dx RP SARS-CoV-2 Negative is intended for use as an external 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* on the QIAstat-Dx[®] Respiratory SARS-CoV-2 Panel performed on QIAstat-Dx systems.

PRODUCT SUMMARY and PRINCIPLE:

QIAstat-Dx RP SARS-CoV-2 Negative contains no nucleic acid.

Routine use of quality controls that are consistent lot to lot assists the laboratory in identifying shifts, trends, and increased frequency of random errors caused by variations in the test system, such as failing reagents. Early investigation can prevent failed assay runs.

COMPOSITION:

The QIAstat-Dx RP SARS-CoV-2 Negative is comprised of 6 tubes of negative control, 300µL each. Table 1 and 2 lists the pathogens that are monitored by the QIAstat-Dx RP SARS-CoV-2 Negative when tested by the QIAstat-Dx Respiratory SARS-CoV-2 Panel on the QIAstat-Dx systems.

INSTRUCTIONS FOR USE:

1. Allow the control to be tested to come completely to room temperature (18° – 25°C).
2. Use the control as provided. DO NOT DILUTE.
3. Prepare a QIAstat-Dx Respiratory SARS-CoV-2 Panel Cartridge according to the QIAstat-Dx Respiratory SARS-CoV-2 Panel Instructions for Use.
4. Open the sample lid of the main port on the front of the QIAstat-Dx Respiratory Panel Cartridge according to the QIAstat-Dx Respiratory SARS-CoV-2 Panel 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. 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 QIAstat-Dx Respiratory SARS-CoV-2 Panel Instructions for Use.

PRECAUTIONS, WARNINGS and LIMITATIONS:

- Do not dilute. Use the control as provided.
- This product is intended for *in vitro* analytical testing.
- This product is only for use with QIAstat-Dx Respiratory SARS-CoV-2 Panel on the QIAstat-Dx systems.
- This product is not intended for use as a substitute for the internal controls provided in the QIAstat-Dx Respiratory SARS-CoV-2 Panel.
- Appearance: 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.
- Quality control materials should be used in accordance with local, state, federal regulations and accreditation requirements.
- QIAstat-Dx RP SARS-CoV-2 Negative cannot be cloned, sold, or transferred without the explicit written consent of MMQCI.

STORAGE and STABILITY:

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

ORDERING INFORMATION:

QIAstat-Dx RP SARS-CoV-2 Negative
 Part Number: M36321-6
 Kit Contains: 6 tubes of Negative x 300µL

EXPECTED VALUES:

Table 1 and Table 2 list the expected results when the controls are analyzed by QIAstat-Dx Respiratory SARS-CoV-2 Panel. *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 Negative in demonstrating adequate system performance.

Table 1: US customers Expected Results for QIAstat-Dx RP SARS-CoV-2 Negative

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

Table 2: NON-US customers Expected Results for QIAstat-Dx RP SARS-CoV-2 Negative

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