



Verigene® RP Flex Control Panel M270

INTENDED USE:

The Verigene® RP Flex Control Panel M270 is intended for in vitro use as a quality control to monitor the amplification, detection and identification of multiple viral and bacterial respiratory pathogens as performed by the VERIGENE® Respiratory Pathogens *Flex* Nucleic Acid Test (RP *Flex*) on the VERIGENE System. Detection of the viruses and bacterial nucleic acids from those organisms listed in Table 1 is an important aid to the diagnosis of individuals exhibiting signs and symptoms of a respiratory infection.

PRODUCT SUMMARY and PRINCIPLE:

Verigene RP Flex Control Panel M270 is composed of 3 controls, Verigene RP Flex Positive A (Positive A), Verigene RP Flex Positive B (Positive B), and Verigene RP Flex Negative. Positive A and Positive B contain synthetic RNA corresponding to genome segments of pathogens listed in Table 1. Verigene RP Flex Negative contains non-target RNA.

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:

Each Verigene RP Flex Control Panel M270 is composed of 4 tubes of Positive A and 4 tubes of Positive B, 200µL each, containing synthetic target RNA suspended in a non-infectious solution of buffers, preservatives and stabilizers, and 4 tubes of Verigene RP Flex Negative, 200µL each, of synthetic non-target RNA suspended in a non-infectious solution of buffers, preservatives and stabilizers. Table 1 lists the pathogens that are monitored by the Verigene RP Flex Control Panel M270 when tested by the RP *Flex* on the VERIGENE System.

STORAGE and STABILITY:

Verigene RP Flex Control Panel M270 should be stored frozen (-25°C to -15°C). Unopened Verigene RP Flex Control Panel M270 is stable through the expiration date printed on the kit label when continuously stored frozen. Verigene RP Flex Positive A M271, Verigene RP Flex Positive B M272, and Verigene RP Flex Negative M273 are for single use. Discard after use according to your local and federal regulations.

PRECAUTIONS and WARNINGS:

- This product is intended for *in vitro* analytical testing and is provided for Research Use Only, not for use in diagnostic procedures.
- Appearance: Cloudy.
- 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.
- Verigene RP Flex Control Panel M270 cannot be cloned, sold, or transferred without the explicit written consent of MMQCI.

INSTRUCTIONS FOR USE:

- Allow the control to be tested to come to room temperature (18° – 25°C).
- Use the control as provided.
- Refer to VERIGENE RP *Flex* Nucleic Acid Test Instructions for detailed instruction on Processor *SP* Set-Up.
- Immediately before use, mix the control by briefly vortexing the tube for 3 – 5 seconds and then shake the tube down firmly to remove any droplets caught in the cap.
- Using a micropipette, pipette 200µL of the control sample into the bottom of the Sample Loading Well in the Extraction Tray.
- After the sample is loaded, place the Sample Well Cap over the Sample Loading Well. Take precaution to handle only the edges of the Cap and firmly press down until the cap is fully inserted into the Sample Loading Well.
- Analyze the control as you would a patient sample by loading the Extraction Tray onto the Processor *SP*.

Note: Per the VERIGENE System User Manual Troubleshooting Chapter: If a “No Call – VARIATION” test result occurs, retest the sample. If the issue is not resolved after retesting, perform a dilution per the Technical Note TN#: 25-001 and Quick Guide MBR071 located in our support section of our website, www.mmqci.com.

- Discard after use according to your local and federal regulations.

EXPECTED VALUES:

The laboratory should follow Good Laboratory Practice (GLP) and establish its own performance characteristics for Verigene RP Flex Control Panel M270 in demonstrating adequate system performance.

The expected results when controls are analyzed are listed in Table 1.

Table 1: Verigene RP Flex Control Panel M270 QC Results

Organism	M27120	M27220	M27320
Influenza A	Not Detected	Detected	Not Detected
Influenza A/H1	Not Detected	Detected	Not Detected
Influenza A/H3	Not Detected	Detected	Not Detected
Influenza B	Not Detected	Detected	Not Detected
RSV A	Not Detected	Detected	Not Detected
RSV B	Not Detected	Detected	Not Detected
Adenovirus	Detected	Not Detected	Not Detected
hMPV	Detected	Not Detected	Not Detected
Parainfluenza 1	Detected	Not Detected	Not Detected
Parainfluenza 2	Detected	Not Detected	Not Detected
Parainfluenza 3	Detected	Not Detected	Not Detected
Parainfluenza 4	Detected	Not Detected	Not Detected
Rhinovirus	Detected	Not Detected	Not Detected
B. para/bronch	N/A	Detected	Not Detected
B. pertussis	Detected	Not Detected	Not Detected
B. holmesii	Detected	Not Detected	Not Detected

ORDERING INFORMATION:

Verigene RP Flex Control Panel M270

Part Number: M270

Kit Contains: 12 tubes x 200µL

4 each of M27120, M27220 & M27320