Verigene® RP Flex Control Panel M270

INTENDED USE:

The Verigene® RP 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.

Best practice is to establish a quality control program for every assay performed by the laboratory.[1, 2] 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. At a minimum, controls should be run at the frequency recommended by the RP *Flex* manufacturer's recommendations for external quality control testing.

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 Postive 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:

- Do not dilute.
- This product is intended for in vitro analytical testing and is provided for Research Use Only, not for use in diagnostic procedures.
- This product does not contain any biological material of human or animal origin. Universal Precautions are NOT required when handling this product.

INSTRUCTIONS FOR USE:

1. Allow the control to be tested to come to room temperature (18° – 25°C).
2. Use the control as provided. ***DO NOT DILUTE.***
3. Refer to Verigene® RP *Flex* Nucleic Acid Test Instructions for detailed instruction on Processor *SP* Set-Up.
4. 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.
5. Using a micropipette, pipette 200uL of the control sample into the bottom of the Sample Loading Well in the Extraction Tray.
6. 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.
7. Analyze the control as you would a patient sample by loading the Extraction Tray onto the Processor *SP*.
8. 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

Maine Molecular Quality Controls, Inc.
23 Mill Brook Road
Saco, ME 04072 USA
Phone: 207-885-1072, FAX: 207-885-1079
Web: www.mmqci.com, Email: info@mmqci.com

1. ISO 15189: Medical laboratories – Particular requirements for quality and competence.
2. CAP Molecular Pathology Checklist; Commission on Laboratory Accreditation, Laboratory Accreditation Program, Mol.20000