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TECHNICAL NOTE # 25-001

RE: Dilution Protocol for the Verigene[®] RP Flex Control Panel M270 when a No Call – VARIATION (NCV) test result occurs

ASSAY: VERIGENE® Respiratory Pathogens *Flex* Nucleic Acid Test (RP *Flex*)

DATE: 06/17/2025

If a "No Call – VARIATION" test result occurs with the Verigene RP Flex Control Panel M270, retest the sample. If the issue is not resolved after retesting, perform a 1:10 dilution as described below.

- 1. Allow the control to be tested to come to room temperature $(18^\circ 25^\circ C)$.
- 2. Pipette 450µL of fresh nuclease-free molecular grade water into high quality polypropylene tube.
- 3. Mix the room temperature control thoroughly by briefly vortexing the tube for 3-5 seconds and then gently tapping the tube on the bench to remove any droplets caught in the cap.
- 4. Using a micropipette, pipette 50μ L of the control into the 450μ L of molecular grade water.
- 5. Mix by pipetting up and down with the same pipette tip.
- 6. Cap and mix the dilution thoroughly by flicking the tube, then vortex 3-5 seconds. Gently tap the dilution tube on the bench to remove any droplets inside the cap.
- 7. Using a micropipette, pipette 200µL of the diluted control sample into the bottom of the Verigene RP Flex 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.
- 8. Analyze the diluted control as you would a patient sample by loading the Extraction Tray on the Processor *SP*.
- 9. <u>Discard all dilutions and open vials.</u> The Verigene RP Control Panel M270 is NOT stable in water so saving dilutions, freezing, and reusing is never recommended. Always discard dilutions the same day they are made.

If the 1:10 diluted control still produces an NCV result, please reach out to MMQCI at <u>info@mmqci.com</u> or 207-885-1072 for further investigation.