PROGRAM Standard Operating Procedure – Laboratory Services	
Title: MIC82300 – BioFire Respiratory Panel 2.1 Quality Control	Policy Number:
Program Name: Laboratory Services	
Applicable Domain: Lab, DI and Pharmacy Services	
Additional Domain(s):	
Effective Date:	Next Review Date:
Issuing Authority: Director of Health Services	Date Approved:
Accreditation Canada Applicable Standard: N/A	

GUIDING PRINCPLE:
Quality control is performed on every new lot number and/or shipment of BioFire Respiratory Panel pouches to ensure proper function and to ensure pouches and reagents have not deteriorated during shipping. Quality control should be rotated through the different modules of the instrument.

PURPOSE/RATIONALE:
This standard operating procedure describes quality control for the Respiratory Panel 2.1 kit on the BioFire FilmArray Torch.

SCOPE/APPLICABILITY:
This procedure applies to Medical Laboratory Technologists processing specimens using the BioFire FilmArray Torch.

REAGENTS and/or MEDIA:
- MMQCI BioFire RP2.1 Control
- BioFire RP2.1 pouch
- Hydration injection vial (blue)
- Sample buffer ampoule
- Sample injection vials (red)
- Transfer pipettes provided in kit
- Accel TB 1 L bottle
- Accel TB wipes
- 70% isopropyl alcohol

SUPPLIES:
- Personal protective equipment
- Absorbent bench liner
- Wet and dry waste containers
- Orange autoclave bags
- Spray bottle
- Sharps container

EQUIPMENT

- BioFire FilmArray Torch
- Class II biosafety cabinet
- Refrigerator

ENVIRONMENTAL CONTROLS:

- Store the test kit, including reagent pouches and buffers, at room temperature (15°C to 25°C) **DO NOT REFRIGERATE**
- Avoid storage of any materials near heating or cooling vents or in direct sunlight
- All kit components should be stored and used together. Do not use components from one kit with those of another kit
- Once the pouch packaging has been opened, the pouch should be loaded with sample as soon as possible (within 30 minutes)
- Once a pouch has been loaded with sample, the test run should be started as soon as possible (within approximately 60 minutes)
- To prevent amplicon contamination: discard used pouches after the run has completed, avoid excessive handling of pouches after test runs and avoid exposing pouches to sharp edges or anything that might cause a puncture

PROCEDURE INSTRUCTIONS:

Step	Action
Performing Respiratory Panel 2.1 Quality Control	
1	Respiratory Panel 2.1 quality control is performed on every new lot number and/or shipment of kits.
2	Enter kit information into TQC. Refer to MIC60090-Entering New Media and Reagents into TQC.
3	Perform quality control testing using MMQCI BioFire RP2.1 Control. The kit includes a positive and a negative control solution and is stored frozen.
4	Quality control is rotated through the different modules of the instrument using the defined schedule. Refer to appendix below.
5	Prepare the RP2.1 pouch as per MIC82200-BioFire Respiratory Panel 2.1 substituting the patient specimen with the control solutions. **NOTE:** Do not run controls with patient samples in order to prevent possible contamination from the positive control solution
6	When creating a test run, manually enter the sample ID as Positive Control or Negative Control.
7	If QC results are acceptable, complete MIC82310-BioFire RP2.1 QC Results Record. Ensure the control lot number, control expiry date, kit lot number, kit expiry date, kit receipt date and module names are filled in along with the results and the performing technologist's initials. Place the current monthly sheet in the PCR Testing Quality Control Results binder.
8	If QC results are not acceptable, ensure controls were not mixed up during loading (ex. positive control run as the negative control). After preliminary investigation, repeat testing.

9	If repeat QC testing is still not acceptable: • Notify the Technical Supervisor – Microbiology for resolution • Contact bioMerieux to determine if issues with kit exist • Until the problem is resolved, patient testing may not be reported

APPENDIX:

BioFire Respiratory Panel 2.1 Quality Control Schedule for Base 1

Run	Module	Control	Run	Module	Control
1	1	Positive	7	4	Positive
2	2	Negative	8	5	Negative
3	2	Positive	9	5	Positive
4	3	Negative	10	6	Negative
5	3	Positive	11	6	Positive
6	4	Negative	12	1	Negative

BioFire Respiratory Panel 2.1 Quality Control Schedule for Base 2

Run	Module	Control	Run	Module	Control
1	1	Positive	7	4	Positive
2	2	Negative	8	5	Negative
3	2	Positive	9	5	Positive
4	3	Negative	10	6	Negative
5	3	Positive	11	6	Positive
6	4	Negative	12	1	Negative

CROSS-REFERENCES:

- MIC60090-Entering New Media and Reagents into TQC
- MIC82200-BioFire Respiratory Panel 2.1
- MIC82310BioFire RP2.1 QC Results Record

REFERENCES:

- Maine Molecular. (September 03, 2021). *BioFire RP2.1/RP2.1plus Control Panel M441* package insert.
- BioFire. *BioFire FilmArray Torch Operator's Manual*, HTFA-PRT-0001-05, March 2020
- Biosafety Advisory Committee. *STHA Biosafety Program Manual*. January 2016

APPROVAL:

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Date

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REVISION HISTORY:

REVISION	DATE	Description of Change	REQUESTED BY
1.0	15 Aug 20	Initial Release	L. Steven