| PROGRAM Standard Operating Procedure – Laboratory Services | |
|---|---|
| Title: MIC60110 – BIOFIRE RP2.1 Quality Control | Policy Number: |
| Program Name: Laboratory Services | |
| Applicable Domain: Lab, DI and Pharmacy Services | |
| Additional Domain(s): NA | |
| Effective Date: | Next Review Date: |
| Issuing Authority: Director, Laboratory and Diagnostic Imaging Services | Date Approved: |
| Accreditation Canada Applicable Standard: NA | |

**Uncontrolled When Printed**

**GUIDING PRINCPLE:**
Quality control is performed on BIOFIRE RP2.1 pouches to ensure proper function on a monthly basis and to ensure new shipments have not deteriorated during shipping. Quality control should be rotated through the different modules of the instrument.

**PURPOSE/RATIONALE:**
This standard operating procedure describes the quality control procedure for the BIOFIRE RP2.1 test on the BIOFIRE TORCH.

**SCOPE/APPLICABILITY:**
This standard operating procedure applies to Medical Laboratory Technologists (MLTs) performing quality control for the BIOFIRE RP2.1 test.

**REAGENTS and/or MEDIA:**
- MMQCI BIOFIRE RP2.1 controls
- BIOFIRE RP2.1 pouches
- Hydration injection vials (blue)
- Sample buffer ampoules
- Sample injection vials (red)
- Accel TB 1 L bottle
- Accel TB wipes
- 70% isopropyl alcohol

**SUPPLIES:**
- Personal protective equipment
- Wet waste container
- Dry waste container
- Orange autoclave bags
- Spray bottle
- Sharps container
- Transfer pipettes provided in kit

**EQUIPMENT:**

- BIOFIRE Torch
- Class II biosafety cabinet (BSC)
- Vortex mixer
- Freezer

**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
- 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 BIOFIRE RP2.1 Quality Control** | |
| **1** | BIOFIRE RP2.1 quality control is performed monthly and upon receipt of new pouches. |
| **2** | Perform quality control testing using MMQCI BIOFIRE RP2.1 controls. The kit includes a positive control and a negative control and is stored frozen. |
| **3** | Quality control is rotated through the different modules of the instrument using the defined schedule. Refer to appendix below. |
| **4** | Prepare the BIOFIRE RP2.1 pouch as per MIC73200-BIOFIRE Respiratory 2.1 (RP2.1) Panel substituting the patient specimen with the control solutions.<br>**NOTE:** Do not run controls with patient samples in order to prevent possible contamination from the positive control solutions |
| **5** | When creating a test run, manually enter the sample ID as Positive Control or Negative Control. |
| **6** | If all QC results are acceptable, complete MIC60111-QC Results Record-BIOFIRE RP2.1. Ensure the control lot number, control expiry date, kit lot number, kit expiry date and module numbers are filled in along with the results, the performing technologist's initials, and the reason for performing (monthly, new lot or new shipment). The yearly QC Results Record is kept in the PCR Testing Completed QC Records binder under the MIC60110-QC Results Record-BIOFIRE RP2.1 tab. |
| **7** | 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. |
| **8** | If repeat QC testing is still not acceptable:<br>• Notify the Technical Supervisor-Microbiology for resolution<br>• Contact bioMerieux to determine if issues with kits exist<br>• Until the problem is resolved, patient testing may not be reported |

**APPENDIX:**
**BIOFIRE RP2.1 Quality Control Schedule**

| Run | Module | Control | Run | Module | Control |
|---|---|---|---|---|---|
| 1 | 1 | Positive | 11 | 6 | Positive |
| 2 | 2 | Negative | 12 | 7 | Negative |
| 3 | 2 | Positive | 13 | 7 | Positive |
| 4 | 3 | Negative | 14 | 8 | Negative |
| 5 | 3 | Positive | 15 | 8 | Positive |
| 6 | 4 | Negative | 16 | 9 | Negative |
| 7 | 4 | Positive | 17 | 9 | Positive |
| 8 | 5 | Negative | 18 | 10 | Negative |
| 9 | 5 | Positive | 19 | 10 | Positive |
| 10 | 6 | Negative | 20 | 1 | Negative |

**CROSS-REFERENCES:**

- MIC60111-QC Results Record-BIOFIRE RP2.1
- MIC73200-BIOFIRE Respiratory 2.1 (RP2.1) Panel

**REFERENCES:**

1. MMQCI. (August 2024). *BIOFIRE RP2.1/RP2.1plus Control Panel* insert
2. BIOFIRE *Respiratory Panel 2.1 (RP2.1)* Instructions for Use. BFR0001-7709-03 September 2023
3. BIOFIRE. *BIOFIRE FilmArray Torch Operator's Manual*, HTFA-PRT-0001-05, March 2020
4. Biosafety Advisory Committee. *STHA Biosafety Program Manual*. January 2016

**APPROVAL:**

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Date

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Director, Laboratory and Diagnostic Imaging Services

**REVISION HISTORY:**

| REVISION | DATE | Description of Change | REQUESTED BY |
|---|---|---|---|
| 1.0 | 15 Aug 20 | Initial Release | L. Steven |
| 2.0 | 17 Oct 22 | Procedure reviewed and updated to reflect QC run weekly as well as when new kits received | L. Steven |
| 3.0 | 16 Apr 24 | Procedure reviewed and updated to reflect QC run monthly not weekly | L. Steven |
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