| PROGRAM Standard Operating Procedure – Laboratory Services | |
|---|---|
| Title: MIC73000 – BIOFIRE TORCH | 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 PRINCIPLE:**
The BIOFIRE TORCH is an automated *in vitro* diagnostic (IVD) device intended to detect multiple nucleic acid targets contained in clinical specimens using nested multiplex PCR (nmPCR) in a closed system.

**PURPOSE/RATIONALE:**
This standard operating procedure describes the BIOFIRE TORCH and its components.

**SCOPE/APPLICABILITY:**
This standard operating procedure applies to Medical Laboratory Technologists (MLTs) processing specimens using the BIOFIRE TORCH.

**SAMPLE INFORMATION:**
- Refer to assay specific BIOFIRE procedures for sample information

**REAGENTS and/or MEDIA:**
- Refer to assay specific BIOFIRE procedures for reagent information

**SUPPLIES:**
- Refer to assay specific BIOFIRE procedures for supply information

**EQUIPMENT:**
- BIOFIRE TORCH
- Printer

**ENVIRONMENTAL CONTROLS:**

- Operating temperature: 15°C to 30°C
- Relative humidity: 20% to 80% relative humidity, non-condensing

**SPECIAL SAFETY PRECAUTIONS:**

Containment Level 2 facilities, equipment, and operational practices for work involving infectious or potentially infectious materials or cultures:

- Ensure that appropriate hand hygiene practices be used
- Lab gown must be worn when performing activities with potential pathogens
- Gloves must be worn when direct skin contact with infected materials is unavoidable
- Eye protection must be used when there is a known or potential risk of exposure of splashes
- All procedures that may produce aerosols or involve high concentrations or large volumes should be conducted in a biological safety cabinet (BSC)
- The use of needles, syringes and other sharp objects should be strictly limited

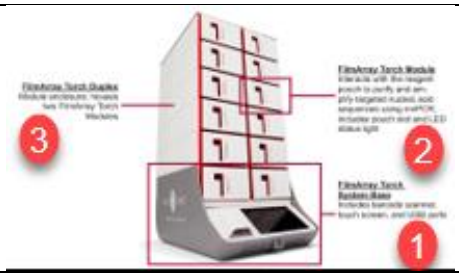
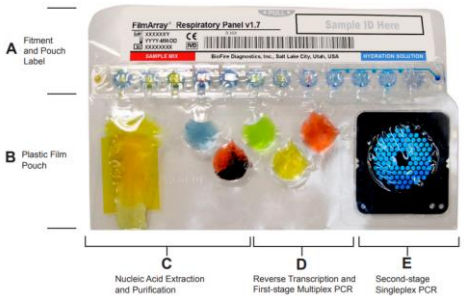
All patient specimens are assumed to be potentially infectious. Routine Practices must be followed. Since viable micro-organisms are used, all cultures must be handled with appropriate precautions. All equipment in contact with cultures should be decontaminated by appropriate methods.

**QUALITY CONTROL:**

- Refer to specific BIOFIRE procedures for quality control information

**PROCEDURE INSTRUCTIONS:**

| Step | Action |
|---|---|
| **System Components** | |
| **1** | **BIOFIRE TORCH Instrument:**<br>• The BIOFIRE TORCH is composed of one to twelve BIOFIRE Modules connected to a BIOFIRE TORCH System Base running BIOFIRE Software<br>• The major components of the BIOFIRE TORCH includes:<br>1. BIOFIRE TORCH System Base-Includes barcode scanner, touch screen and USB ports. The BIOFIRE TORCH System Base houses up to two BIOFIRE Modules.<br>2. BIOFIRE Module-Interacts with the reagent pouch to purify and amplify targeted nucleic acid sequences using nmPCR, includes pouch slot and LED status light. Each BIOFIRE Module can be randomly and independently accessed to run a reagent pouch.<br>3. BIOFIRE TORCH Duplex-Module enclosure; houses up to two BIOFIRE Modules. Up to five BIOFIRE TORCH Duplex Module enclosures, each capable of housing up to two additional BIOFIRE Modules, may be added on top of the BIOFIRE TORCH System Base. |

| | |
|---|---|
| |  |
| **2** | **BIOFIRE Pouch:**<br>• Each BIOFIRE Pouch is a self-contained, closed-system disposable packet that houses all the chemistry required to isolate, amplify and detect nucleic acid from a sample<br>• The reservoirs in the rigid plastic component or fitment of the pouch (A) contain freeze-dried reagents<br>• The flexible plastic film portion of the pouch (B) is divided into discrete segments (blisters) which, via interactions with actuators and sensors in the BIOFIRE Module, are where the chemical processes are performed:<br>➢ (C) Extraction and purification of nucleic acids from a clinical sample using mechanical lysis (bead beating) and magnetic bead technology<br>➢ (D) First-stage multiplex PCR (including reverse transcription of target RNAs when appropriate)<br>➢ (E) Second stage singleplex PCR and melting analysis within a multi-well array:<br>  <br><br>• Each pouch contains at least one internal process control. Control material is lysed, and the nucleic acids of the control material are extracted along with that of the organisms contained in the sample. When the internal control is positive, proper operation of the BIOFIRE Module and chemical processes have been demonstrated |
| **3** | **Mechanical Lysis:**<br>• The first step in processing a sample is to break the outer membrane of the target cells contained in the sample using a device called a bead-beater<br>• A sensor detects the speed and operation of the bead-beater motor and aborts the run if the bead-beater is not working properly |
| **4** | **Nucleic Acid Extraction:**<br>• Following bead-beating, the nucleic acids contained in the sample are purified by magnetic bead technology<br>• A retractable magnet is used to capture or release the magnetic beads during washes |

| | |
|---|---|
| **5** | **Thermal Control:**<br>• The purified nucleic acids are mixed with PCR reagents, which amplify all of the targets identified by the pouch as well as the control material<br>• A Peltier device drives the thermocycling of the reverse transcription and/or PCR reactions<br>• A second Peltier device controls thermocycling for second-stage PCR and DNA melting |
| **6** | **Optics and Imaging:**<br>• To identify targets from positive PCR reactions, DNA melting curve analysis is performed<br>• The fluorescence emitted by the dye is imaged by a camera<br>• DNA melting curves are captured by slowly increasing the temperature of the PCR array and capturing the fluorescent signal<br>• These images are processed automatically by the System Base and the data is analyzed to determine if the control reactions passed and which targets were detected in the sample<br>• Proper operation and calibration of BIOFIRE Module optics is monitored by the BIOFIRE Module self-tests and internal controls |
| **7** | **BIOFIRE TORCH Software:**<br>• The BIOFIRE TORCH Software controls the function of each Module<br>• The software also collects, stores and analyzes data generated by the BIOFIRE Module<br>• Results of analyses are presented in a test report<br>• The BIOFIRE TORCH Software automatically starts when the BIOFIRE TORCH is powered on – no login is required<br>• The BIOFIRE TORCH Toolbar always displays at the top of the screen and consists of three options:<br>➢ Dashboard-Displays the status of each BIOFIRE Module within the BIOFIRE TORCH and guides the operator through the process of operating the modules. The dashboard also displays the status of all runs that are in progress, along with the sample ID, pouch type and time remaining until completion<br>➢ Browse Runs-Allows operators to search for runs and perform operations on individual runs or on group of runs. The runs are presented as a table that lists the date of the run, sample ID and other information about the run<br>➢ Settings-Allows users to perform administrative type tasks, such as print options, managing operators, pouch modules, instrument modules, archive, view system logs and switch to admin mode |
| **8** | **BIOFIRE TORCH Module Status:**<br>• Solid white light → Module is initializing<br>• Solid yellow light → Warning, i.e., not connected<br>• Solid blue light → Module idle and available to run a pouch<br>• Blinking blue light → Module waiting for pouch insertion<br>• Fast blinking green light → Pouch inserted but run not started yet<br>• Solid green light → Run in progress<br>• Slow blinking green light → Run complete, remove pouch<br>• Solid red light → Error. Operator intervention required |

**INTERPRETATION OF RESULTS:**

- Refer to assay specific BIOFIRE procedures for interpretation of results

**REPORTING INSTRUCTIONS:**

- Refer to assay specific BIOFIRE procedures for reporting of results

**CROSS REFERENCES:**

NA

**REFERENCES:**

1. BIOFIRE TORCH Operator's Manual, HTFA-PRT-0001-05, March 2020

**APPROVAL:**

_____

Date

_____

Director, Laboratory and Diagnostic Imaging Services

**REVISION HISTORY:**

| REVISION | DATE | Description of Change | REQUESTED BY |
|---|---|---|---|
| 1.0 | 10 Aug 20 | Initial Release | L. Steven |
| 2.0 | 17 Oct 22 | Procedure reviewed | L. Steven |
| 3.0 | 01 Oct 24 | Procedure reviewed | L. Steven |
| | | | |
| | | | |
| | | | |
| | | | |