Example Individualized Quality Control Plan (IQCP) Risk Analysis for the BIOFIRE® SPOTFIRE® Respiratory (R) Panel, the BIOFIRE® SPOTFIRE® Respiratory (R) Panel Mini, the BIOFIRE® SPOTFIRE® Respiratory/Sore Throat (R/ST) Panel, and the BIOFIRE® SPOTFIRE® Respiratory/Sore Throat (R/ST) Panel Mini

1. Introduction

The Clinical Laboratory Improvement Amendments (CLIA), passed in 1988, establishes quality standards for all laboratory testing to ensure the accuracy and reliability of patient test results, regardless of where the test is performed. CLIA regulations require a laboratory to have quality control (QC) procedures to monitor the accuracy and precision of the complete testing process. The Individualized Quality Control Plan (IQCP) is an optional program allowing laboratories the opportunity to develop a quality control plan that is unique to their testing process. An IQCP includes a risk assessment, a quality control plan, and quality assessment. The risk assessment evaluates all the possible sources of failure or error in the testing process. This document provides an example IQCP risk assessment for the BIOFIRE® SPOTFIRE® System running the BIOFIRE® SPOTFIRE® Respiratory (R) Panel, the BIOFIRE® SPOTFIRE® Respiratory (R) Panel Mini, the BIOFIRE® SPOTFIRE® Respiratory/Sore Throat (R/ST) Panel, and the BIOFIRE® SPOTFIRE® Respiratory/Sore Throat (R/ST) Panel Mini. Laboratories can use the examples in this document as a starting point for their IQCP risk analysis but must develop their own risk assessment. The examples in this document may not identify all the sources of failure or error in using the SPOTFIRE Respiratory and Sore Throat Panels with the SPOTFIRE System, as each laboratory may have unique environments, personnel, and patients.

This guideline references the following documents:
BIOFIRE® SPOTFIRE® Respiratory (R) Panel Instructions for Use (Instructions for Use): BFR0002-2457
BIOFIRE® SPOTFIRE® Respiratory (R) Panel Mini Instructions for Use (Instructions for Use): BFR0002-1771
BIOFIRE® SPOTFIRE® Respiratory/Sore Throat (R/ST) Panel Instructions for Use (Instructions for Use): BFR0000-2787
BIOFIRE® SPOTFIRE® Respiratory/Sore Throat (R/ST) Panel Mini Instructions for Use (Instructions for Use): BFR0002-5495
BIOFIRE® SPOTFIRE® Respiratory (R) Panel Quick Guide (Quick Guide): BFR0002-1763
BIOFIRE® SPOTFIRE® Respiratory (R) Panel Mini Quick Guide (Quick Guide): BFR0002-1770
BIOFIRE® SPOTFIRE® Respiratory/Sore Throat (R/ST) Panel Quick Guide (Quick Guide): BFR0002-5494
BIOFIRE® SPOTFIRE® Respiratory/Sore Throat (R/ST) Panel Mini Quick Guide (Quick Guide): BFR0002-5496

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BIOFIRE® SPOTFIRE® System Operator Manual (System Operator Manual): BFR0001-1641
College of American Pathology Laboratory General Checklist, 2024 edition
State Operations Manual-Appendix C-CMS

2. Information and Resources for Risk Assessment

According to the guide published by the CDC "Developing an IQCP a Step-by-Step Guide," information and resources including but not limited to the following should be reviewed for the risk assessment.

- Laboratory procedures/standard operating procedures (SOPs)
- Manufacturer's instructions/package inserts
- Instrument and troubleshooting manuals
- Manufacturer's alerts and bulletins
- Calibration data
- Data obtained through verification or establishment of performance specifications
- FDA alerts
- Historical QC data, including data from a previously conducted equivalent quality control study
- Instrument correlation data
- Proficiency Testing results and data
- Records of complaints and corrected reports
- Regulatory and accreditation requirements
- Scientific publications
- Test process flow charts or maps
- Testing personnel training and competency records

3. Recommended QC Frequency

The frequency of QC testing should be determined as part of developing an individualized quality control plan but must be in accordance with the following regulatory guidelines:

1. The laboratory complies with quality control requirements as designated by the manufacturer and regulatory authorities.
2. For multiplex tests, external control materials must be analyzed with new lots and shipments of reagents.
3. The laboratory performs daily testing of positive and negative controls unless the test contains an internal quality control process (e.g. electronic/procedural/built-in) and the laboratory has an individualized quality control plan (IQCP) approved by the laboratory director to address the use of the alternative control system to meet the daily external quality control requirement.
4. The QC study to assess the performance and stability of the tests must support the QC frequency and elements defined in the laboratory's quality control plan.
5. The Laboratory should document provisions for multiple identical devices and variation for uses covered under one IQCP.

Note: When historical QC data is not available, laboratories can refer to various regulatory guidelines for running an equivalent quality control study.

The Laboratory Director is responsible to assure that the laboratory complies with all quality control requirements for each assay.

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4. Example Risk Analysis-Pre-Analytical Phase

Phase of Testing: Pre-Analytical					
Risk Assessment Component: Specimen					
Risk Assessment Subcomponent	**Manufacturer's Recommendations and Precautions**	**Source of Manufacturer's Information**	**Possible Error(s)**	**Possible Risk due to Error**	**How can errors or risks be reduced?**
Specimen Type	Nasopharyngeal swab (NPS) or anterior nasal swab (ANS) collected according to standard technique and immediately placed in 3 mL of transport medium.	Instructions for Use, Sample Requirements	Sample type does not meet intended use.	Risk of incorrect test results.	
	Throat swab (TS) collected according to standard technique and immediately placed in 1 mL of transport medium.				
Specimen Collection	Specimens should not be centrifuged before testing.	Instructions for Use, Sample Requirements	An improperly collected specimen can increase the risk of a false negative test result.	Risk of false negative test results.	
	Minimum sample volume is 0.3 mL (300µL).		Insufficient sample volumes can increase the risk of a false negative test result.		
	Bleach can damage organisms/nucleic acids within the specimen, potentially causing false negative results. Contact between bleach and specimens during collection, disinfection, and testing procedures should be avoided.		Degraded organisms/ nucleic acids can lead to false negative test results.		
	The detection of viral and bacterial nucleic acid is dependent upon proper specimen collection, handling, transportation, storage, and preparation. Failure to observe proper procedures in any one of these steps can lead to incorrect results. There is a risk of false positive or false negative values resulting from improperly collected, transported, or handled specimens.	Instructions for Use, Limitations	There is a risk of false positive or false negative values resulting from improperly collected, transported, or handled specimens.	Risk of false positive or false negative test results.	

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Phase of Testing: Pre-Analytical					
Risk Assessment Component: Specimen					
Risk Assessment Subcomponent	**Manufacturer's Recommendations and Precautions**	**Source of Manufacturer's Information**	**Possible Error(s)**	**Possible Risk due to Error**	**How can errors or risks be reduced?**
Media and Swabs	The SPOTFIRE R Panel and the SPOTFIRE R Panel Mini have not been validated for testing of specimens other than nasopharyngeal swab (NPS) specimens in transport medium. The SPOTFIRE R/ST Panel has not been validated for testing of specimens other than nasopharyngeal swab (NPS) or throat swab (TS) specimens in transport medium. The SPOTFIRE R/ST Panel Mini has not been validated for testing of specimens other than nasopharyngeal swab (NPS), anterior nasal swab (ANS), or throat swab (TS) specimens in transport medium	Instructions for Use, Limitations	Specimen type does not meet intended use.	Risk of false positive or false negative test results.	
	The media and swabs listed in the IFU were validated for use with the SPOTFIRE R Panel, the SPOTFIRE R Panel Mini, the SPOTFIRE R/ST Panel, and the SPOTFIRE R/ST Panel Mini, however, other commercial liquid media and swab types may be appropriate. See the Interference section for more details.	Instructions for Use, Materials Required but not provided, and Interference	Improper media or swabs are used.	Risk of false positive or false negative test results.	
	Transport media may contain non-viable organisms and/or nucleic acids at levels that can be detected by the SPOTFIRE R Panel, the SPOTFIRE R Panel Mini, the SPOTFIRE R/ST Panel, and the SPOTFIRE R/ST Panel Mini.	Instructions for Use, Laboratory Precautions, and Limitations	Risk of false positive test result from media.	Risk of false positive test results.	
Specimen Storage	Specimens should be tested as soon as possible. If storage is required, specimens can be held: • At room temperature for up to 4 hours (15-25°C) • Refrigerated for up to 3 days (2-8°C) • Frozen (≤-15°C) (for up to 30 days)	Instructions for Use, Sample Requirements	There is a risk of false positive or false negative values resulting from improperly collected, transported, or handled specimens.	Risk of false positive or false negative test results.	
Risk Assessment Component: Reagent Stability and Test System					
Risk Assessment Subcomponent	**Manufacturer's Recommendations and Precautions**	**Source of Manufacturer's Information**	**Possible Error(s)**	**Possible Risk due to Error**	**How can errors or risks be reduced?**
Prepare Pouch	Thoroughly clean the work area and the Pouch Loading Station with freshly prepared 10% bleach (or suitable disinfectant) followed by a water rinse.	Instructions for Use, Procedure: Step 1 Prepare Pouch; Laboratory Precautions; and Quick Guide, Contamination Precautions	Risk that contamination is introduced during sample loading.	Risk of false positive test results.	

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4. Example Risk Analysis- Pre-Analytical Phase continued

Phase of Testing: Pre-Analytical					
Risk Assessment Component: Reagent Stability and Test System					
Risk Assessment Subcomponent	**Manufacturer's Recommendations and Precautions**	**Source of Manufacturer's Information**	**Possible Error(s)**	**Possible Risk due to Error**	**How can errors or risks be reduced?**
Prepare Pouch	Specimens and pouches should be handled and/or tested one-at-a-time. Always change gloves and clean the work area between each pouch and specimen.	Instructions for Use, Laboratory Precautions; and Quick Guide, Contamination Precautions	Risk that contamination is introduced during sample loading.	Risk of false positive test results.	
	Prepare Pouch and Hydrate according to Instructions for Use:	Instructions for Use, Procedure: Step 1 Prepare Pouch and Step 2 Hydrate Pouch; and Quick Guide, Step 2: Prepare SPOTFIRE Panel Pouch, Step 3: Hydrate SPOTFIRE Panel Pouch	Risk that pouch fails to hydrate.	No test results obtained.	Verify that pouch has been hydrated by following instructions in the Instructions for Use or the Quick Guide.
	• The pouch may still be used even if the vacuum seal of the pouch is not intact. Attempt to hydrate the pouch using the steps in the Hydrate Pouch section. If hydration is successful, continue with the run. If hydration fails, discard the pouch and use a new pouch to test the sample.				
	• Note: Some hydration solution may remain in the Hydration Injection Vial.				
	• Do not cover the pouch barcode located on the left side of the label with the sample ID.		Increased risk of entry errors when pouch type and protocol are entered manually.	Risk of erroneous test results.	
Prepare Patient or QC Sample	**Prepare Patient or QC Sample according to Instructions for Use:**	Instructions for Use, Procedure: Step 3 Prepare Patient or QC Sample; and Quick Guide, Step 4: Prepare and Load Patient or QC Sample	Risk that insufficient sample volume is added to Sample Injection Vial.	Risk of false negative test results.	
	• Use the fixed-volume transfer pipette to draw in the correct amount of liquid (approximately 0.3 mL).				
	• In rare cases, the fixed-volume Transfer Pipette may not draw the correct amount of liquid. If the liquid volume is not drawn approximately one-third up the length of the stem of the fixed-volume Transfer Pipette, discard it and retrieve a new fixed-volume Transfer Pipette from another SPRK package.				

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4. Example Risk Analysis- Pre-Analytical Phase continued

Phase of Testing: Pre-Analytical					
Risk Assessment Component: Reagent Stability and Test System					
Risk Assessment Subcomponent	**Manufacturer's Recommendations and Precautions**	**Source of Manufacturer's Information**	**Possible Error(s)**	**Possible Risk due to Error**	**How can errors or risks be reduced?**
Prepare Patient or QC Sample	• To avoid contamination, do not touch the open tip of the Sample Buffer ampoule.	Instructions for Use, Procedure: Step 3 Prepare Patient or QC Sample; and Quick Guide, Step 4: Prepare and Load Patient or QC Sample	Increased risk that contamination is introduced during sample preparation.	Risk of false positive test results.	
	CAUTION—The Sample Buffer is harmful if swallowed and can cause serious eye damage and/or skin irritation. Use appropriate PPE.		Risk of eye damage and/or skin irritation in testing personnel.	Risk of injury to testing personnel.	Use appropriate PPE.
Prepare QC Sample	**QC specific information:**	Instructions for Use, Procedure: Step 3 Prepare Patient or QC Sample; and Quick Guide, Step 4: Prepare and Load Patient or QC Sample	Increased risk that contamination is introduced during sample preparation.	Risk of erroneous QC test results.	
	• Positive QC materials are a PCR contamination risk.				
	• When performing QC testing, some liquid may be leftover in the QC material tube.				
	• The Positive QC test should be run before the Negative QC test.	Instructions for Use, External Controls: Quality Control Testing; and Quick Guide, Quality Control Testing Instructions	The Negative QC test will monitor for potential environmental contamination introduced by the Positive QC test. Running the negative QC after the positive QC reduces the risk of unmonitored environmental contamination.		
	• Positive and Negative QC barcodes are different and using the wrong barcode will lead to incorrect results.		Risk of incorrect test results if the wrong barcode used.		
	• QC Testing should only be performed after selecting the QC icon at the top of the screen and following on-screen instructions.	Instructions for Use, Procedure: Step 5: Start Run; and Quick Guide, Quality Control Testing Instructions and Step 5: Run Test on SPOTFIRE SYSTEM	Failure to run QC sample using the QC workflow may lead to erroneous QC test results.		

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4. Example Risk Analysis- Pre-Analytical Phase continued

Phase of Testing: Pre-Analytical					
Risk Assessment Component: Reagent Stability and Test System					
Risk Assessment Subcomponent	**Manufacturer's Recommendations and Precautions**	**Source of Manufacturer's Information**	**Possible Error(s)**	**Possible Risk due to Error**	**How can errors or risks be reduced?**
Load Patient or QC Sample	Load Patient or QC Sample according to Instructions for Use:	Instructions for Use, Procedure: Step 4 Load Patient or QC Sample; and Quick Guide, Step 4: Prepare and Load Patient or QC Sample.	Increased risk that contamination is introduced during sample preparation.	Risk of work area contaminati on and false positive test results.	Pausing reduces the risk of contaminati on.
	• Slowly twist to unscrew the Sample Injection Vial and pause for 5 seconds with the blunt needle remaining in cap to avoid dripping.				
	• Note: Pausing 5 seconds decreases the risk of dripping and contamination from the sample.				
	• Note: To avoid contamination, do not touch the tip of blunt needle.				
	• Verify that the sample has been loaded.		Risk that sample is not properly loaded.	Risk of false negative test results.	Verify that the sample has been loaded by following instructions.
	• Note: Some sample mix may remain in the Sample Injection Vial.				
Reagent Storage	• Store the test kit, including reagent pouches and buffers, at room temperature (15–25 ºC).	Instructions for Use, Reagent Storage, Handling, and Stability	Improper reagent storage conditions can increase risk of inaccurate test result.	Risk of inaccurate test results.	
	• 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. Discard any extra components from the kit after all pouches have been consumed.				
Pouch Handling and Stability After Opening / Loading	• Do not remove pouches from their packaging until a sample is ready to be tested. Once the pouch packaging has been opened, the pouch should be loaded as soon as possible (within approximately 30 minutes).	Instructions for Use, Reagent Storage, Handling, and Stability	Improper reagent handling can increase risk of inaccurate test result.	Risk of inaccurate test results.	
	• A desiccant packet is included in each pouch canister to preserve the stability of the SPOTFIRE R/ST Panel. Do not use a pouch if a desiccant packet is not present in the can.				
	• Once a pouch has been loaded, the test run should be started as soon as possible (within approximately 60 minutes). Do not expose a loaded pouch to temperatures above 40°C (104°F) prior to testing.				

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4. Example Risk Analysis- Pre-Analytical Phase continued

Phase of Testing: Pre-Analytical					
Risk Assessment Component: Reagent Stability and Test System					
Risk Assessment Subcomponent	**Manufacturer's Recommendations and Precautions**	**Source of Manufacturer's Information**	**Possible Error(s)**	**Possible Risk due to Error**	**How can errors or risks be reduced?**
Reagent Expiration	Always check the expiration date on the kit and do not use reagents beyond the expiration date printed on the pouch or kit. A warning message will be displayed if the barcode of an expired pouch is scanned.	Instructions for Use, Reagent Storage, Handling, and Stability; Procedure: Step 1 Prepare Pouch; General Precautions; System Operator Manual: Preventative Maintenance and Troubleshooting: Pouch Troubleshooting, Warning Messages	Use of expired reagents can increase risk of inaccurate test results.	Risk of inaccurate test results.	Dispose of any pouch that has expired and use a non-expired pouch.
	Always check the expiration date for the QC material. A warning message will be displayed if the barcode of an expired QC material is scanned.				Dispose of any QC material that has expired and use a non-expired QC reagent material.
Pouch Lot Lockout	If enabled- the initial lot lockout feature will prevent/ restrict a pouch lot from being used for patient tests until passing positive and negative QC tests have occurred for that lot. An on-screen error message will be displayed if the pouch lot is locked out.	System Operator Manual: Quality Control Tab; Lot Lockout and Preventative Maintenance and Troubleshooting: Pouch Troubleshooting, Warning Messages	If lot lockout is enabled, a patient pouch run will not initiate until a passing positive and negative QC has been performed for the pouch lot.	Potential delay or loss of patient sample test results.	Perform QC tests when new pouch lots are received.

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4. Example Risk Analysis- Pre-Analytical Phase continued

Phase of Testing: Pre-Analytical					
Risk Assessment Component: Environment					
Risk Assessment Subcomponent	**Manufacturer's Recommendations and Precautions**	**Source of Manufacturer's Information**	**Possible Error(s)**	**Possible Risk due to Error**	**How can errors or risks be reduced?**
Preventing Organism Contamination	Refer to Instructions for Use for guidelines on preventing organism contamination:	Instructions for Use, Laboratory Precautions	Risk of erroneous false positive test results obtained and reported due to contamination of the environment with organism.	Risk of false positive test results.	
	• Personnel collecting and/or testing specimens may carry or shed common respiratory pathogens asymptomatically and can inadvertently contaminate the specimen while it is being processed. Careful adherence to the sample processing steps described in this document is recommended to avoid possible contamination. Samples may be processed in a clean biosafety cabinet (if available) or according to local/laboratory guidelines. If a biosafety cabinet is not used, a dead air box (e.g., AirClean PCR workstation), a splash shield (e.g., Bel-Art Scienceware Splash Shields), or a face shield may be used when preparing samples.				
	• Personnel with active respiratory symptoms (runny nose, cough) should wear a standard surgical mask (or equivalent) and should avoid touching the mask while handling specimens.				
	• It is recommended to avoid handling specimens or pouches in an area used to routinely process respiratory pathogen culture, and/or immunofluorescence testing, unless the area is thoroughly cleaned first.				
	• Prior to processing specimens, thoroughly clean both the work area and the Pouch Loading Station using a suitable cleaner such as freshly prepared 10% bleach or a similar disinfectant. To avoid residue build-up and potential damage to the specimen or interference from disinfectants, wipe disinfected surfaces with water.	Instructions for Use, Laboratory Precautions; Quick Guide: Contamination Precautions			
	• Specimens and pouches should be handled and/or tested one-at-a-time. Always change gloves and clean the work area between each pouch and specimen.				

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4. Example Risk Analysis- Pre-Analytical Phase continued

Phase of Testing: Pre-Analytical					
Risk Assessment Component: Environment					
Risk Assessment Subcomponent	**Manufacturer's Recommendations and Precautions**	**Source of Manufacturer's Information**	**Possible Error(s)**	**Possible Risk due to Error**	**How can errors or risks be reduced?**
Preventing Organism Contamination	• Use clean gloves when removing Sample Buffer ampoules and Sample/Hydration Injection Vials from the SPRK package. • Avoid collecting or handling specimens in areas that are exposed to vaccine material for pathogens detected by the SPOTFIRE R Panel, the SPOTFIRE R Panel Mini, the SPOTFIRE R/ST Panel, or the SpotFire R/ST Panel Mini (e.g. influenza, SARS-CoV-2, Bordetella pertussis, and poliovirus (Human Rhinovirus/Enterovirus)). Vaccines may contain PCR-detectable DNA or RNA. If possible, particular care should be taken to avoid contamination of the specimen or testing areas (especially with nasal spray vaccines such as FluMist® and B. pertussis acellular vaccines such as Pentacel®, Daptacel®, and Adacel®; http://www.cdc.gov/pertussis/clinical/diagnostic-testing/diagnosis-pcr-bestpractices.html). Contamination of specimens or testing materials with vaccine can cause false-positive results.	Instructions for Use, Laboratory Precautions	Risk of erroneous false positive test results obtained and reported due to contamination of the environment with organism.	Risk of false positive test results.	
Preventing Amplicon Contamination	Refer to Instructions for Use for guidelines on preventing amplicon contamination: • Discard used pouches in a biohazard container immediately after the run has completed. • Avoid excessive handling of pouches after test runs. • Change gloves after handling a used pouch. • Avoid exposing pouches to sharp edges or anything that might cause a puncture.	Instructions for Use, Laboratory Precautions; Quick Guide: Contamination Precautions	Risk of erroneous false positive test results caused by contamination of the work area with PCR amplicon.	Risk of false positive test results.	

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4. Example Risk Analysis-Pre-Analytical Phase continued

Phase of Testing: Pre-Analytical					
Risk Assessment Component: Testing Personnel					
Risk Assessment Subcomponent	**Manufacturer's Recommendations and Precautions**	**Source of Manufacturer's Information**	**Possible Error(s)**	**Possible Risk due to Error**	**How can errors or risks be reduced?**
Competency	Refer to guidelines set by the regulatory body governing your laboratory for user competency requirements for FDA Moderate Complexity or CLIA Waived Tests.	CMS, Appendix C 42CFR §493.1235	Inadequate training to perform testing without errors.	Risk of inaccurate test results.	

5. Example Risk Analysis- Analytical Phase

Phase of Testing: Analytical					
Risk Assessment Component: Test System					
Risk Assessment Subcomponent	**Manufacturer's Recommendations and Precautions**	**Source of Manufacturer's Information**	**Possible Error (s)**	**Possible Risk due to Error**	**How can errors or risks be reduced?**
Start a Patient Test Run	The BIOFIRE® SPOTFIRE® Software includes step-by-step, on-screen instructions that guide the operator through performing a run. • Once a pouch has been prepared for testing, select an available Module on the Home Screen and follow on-screen instructions to run test.	Instructions for Use, Procedure: Step 5 Start Run; System Operator Manual: SPOTFIRE System Test Procedure: Start Test; and Quick Guide Step 5: Run Test on SPOTFIRE System	Risk that test run not initiated.	Risk that no test results are obtained.	Follow on-screen instructions.
	Enter Pouch information: • Scan the barcode on the pouch using the barcode scanner. • If it is not possible to scan the barcode, the pouch Lot Number, Serial Number, Expiration Date, and Pouch Type can be manually entered from the information provided on the pouch label into the appropriate fields.	Instructions for Use, Procedure: Step 5 Start Run; System Operator Manual: SPOTFIRE System Test Procedure: Start Test	Increased risk of incorrect pouch type and protocol entered with manual entry.	Risk of incorrect test result.	
	Enter Sample ID: • The Sample ID can be entered manually or scanned in by using the barcode scanner when a barcoded Sample ID is used.	Instructions for Use, Procedure: Step 5 Start Run; System Operator Manual: SPOTFIRE System Test Procedure: Start Test	Increased risk of incorrect sample ID with manual entry.	Risk that test result is not correlated to correct patient.	
	• Select the appropriate sample type (e.g. Nasal Swab/ Nasopharyngeal Swab or Throat Swab).		Failure to select the appropriate sample type will lead to incorrect test results.	Risk of incorrect test result.	

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5. Example Risk Analysis-Analytical Phase continued

Phase of Testing: Analytical					
Risk Assessment Component: Test System					
Risk Assessment Subcomponent	**Manufacturer's Recommendations and Precautions**	**Source of Manufacturer's Information**	**Possible Error (s)**	**Possible Risk due to Error**	**How can errors or risks be reduced?**
Start a Patient Test Run	• If running QC samples, select the QC icon at the top of the screen and follow on-screen instructions.	Instructions for Use, Procedure: Step 5 Start Run	Risk that QC material is run in patient workflow.	Risk of erroneous QC test results.	Follow on-screen instructions.
	Select any available Module on the Home Screen and follow on-screen instructions to run SPOTFIRE R Panel, SPOTFIRE R Panel Mini, SPOTFIRE R/ST Panel, or the SPOTFIRE R/ST Panel Mini test:	Instructions for Use, Procedure: Step 5 Start Run; Quick Guide: Step 5: Run Test on SPOTFIRE System; and System Operator Manual: SPOTFIRE System Test Procedure: Start Test	Risk that if Module is not ready, the pouch will not be accepted, and the test run will not be started.	Risk of no test result if test run is not started.	
	• Insert the pouch into the Module that is blinking blue. The Module will grab onto the pouch and pull it into the chamber and automatically start the run.	Instructions for Use, Procedure: Step 5 Start Run; and System Operator Manual: SPOTFIRE System Test Procedure: Start Test			Verify the pouch has been accepted into the Module.
	• The selected Module's front panel LED will turn solid green to indicate that the run is in progress.				Verify that the Module's front panel LED is solid green indicating that the run is in progress.
Start a QC Test Run	The BIOFIRE® SPOTFIRE® Software includes step-by-step, on-screen instructions that guide the operator through performing a QC Test run.	Instructions for Use, External Controls: Quality Control Testing Instructions; Quick Guide, Quality Control (QC) Testing Instructions and Step 5: Run Test on SPOTFIRE SYSTEM and System Operator Manual: SPOTFIRE Software Quality Control Tab			
	• Once a pouch has been prepared for testing, select the QC graphic/icon at the top of the Home screen and follow on-screen instructions:		Failure to select QC icon may result in incorrect QC test results and QC data will be stored in Patient Test Results database.	Risk of erroneous QC test results and QC test results not stored in QC Test results database.	
	• Select appropriate QC test (Negative QC or Positive QC) then select an available Module.		Risk of incorrect QC test results if inappropriate QC test selected.	Risk of erroneous QC test results.	

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5. Example Risk Analysis-Analytical Phase continued

Phase of Testing: Analytical					
Risk Assessment Component: Test System					
Risk Assessment Subcomponent	**Manufacturer's Recommendations and Precautions**	**Source of Manufacturer's Information**	**Possible Error (s)**	**Possible Risk due to Error**	**How can errors or risks be reduced?**
Start a QC Test Run	• The Positive QC test should be run before the Negative QC test.	Instructions for Use, External Controls: Quality Control Testing Instructions; Quick Guide Quality Control Testing Instructions	The Negative QC test will monitor for potential environmental contamination introduced by the Positive QC test. Running the negative QC after the positive QC reduces the risk of unmonitored environmental contamination.	Risk of unmonitored environmental contamination.	
	Enter Pouch information: • Scan the barcode on the pouch using the barcode scanner. • If it is not possible to scan the barcode, the pouch Lot Number, Serial Number, Expiration Date, and Pouch Type can be manually entered from the information provided on the pouch label into the appropriate fields.	Instructions for Use, Procedure: Step 5 Start Run; System Operator Manual: SPOTFIRE System Test Procedure: Start Test	Increased risk of incorrect pouch type and protocol entered with manual entry.	Risk of incorrect test result.	Follow on-screen instructions.
	Enter QC Material Barcode: • The QC Material barcode can be entered manually or scanned in by using the barcode scanner. • If the barcode scanner is not available or the barcode is unreadable, manually enter the QC material type (positive or negative), vendor name, vendor part number, QC identifier (panel name), lot number, and expiration date printed on the control material box.	Instructions for Use, External Controls: Quality Control Testing Instructions; Quick Guide, Quality Control Testing Instructions; System Operator Manual: SPOTFIRE Software: Quality Control Tab	Increased risk of incorrect QC test material information with manual entry.	Incorrect QC information stored for QC test run.	
	Note: Positive and Negative QC barcodes are different and using the wrong barcode will lead to incorrect results.	Instructions for Use, External Controls: Quality Control Testing Instructions; and Quick Guide, Quality Control Testing Instructions	Risk of running positive QC material in negative QC workflow or running negative QC material in positive QC workflow.	Incorrect QC test Result.	Follow on-screen instructions.

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5. Example Risk Analysis-Analytical Phase continued

Phase of Testing: Analytical					
Risk Assessment Component: Test System					
Risk Assessment Subcomponent	**Manufacturer's Recommendations and Precautions**	**Source of Manufacturer's Information**	**Possible Error (s)**	**Possible Risk due to Error**	**How can errors or risks be reduced?**
Start a QC Test Run	• Insert the pouch into the Module that is blinking blue. The Module will grab onto the pouch and pull it into the chamber and automatically start the run. • The selected Module's front panel LED will turn solid green to indicate that the run is in progress.	Instructions for Use, Procedure: Step 5 Start Run; and System Operator Manual: SPOTFIRE System Test Procedure: Start Test	Risk that if Module is not ready, the pouch will not be accepted, and the QC test run will not be started.	Risk of no QC test result if test run is not started.	Verify the pouch has been accepted into the Module. Verify that the Module's front panel LED is solid green indicating that the run is in progress.
Pouch Lot Lockout	If enabled- the initial lot lockout prevents/ restricts a pouch lot from being used for patient tests until passing positive and negative QC tests have occurred for that lot. An on-screen error message will be displayed if the pouch lot is locked out.	System Operator Manual: Quality Control Tab; Lot Lockout and Preventative Maintenance and Troubleshooting: Pouch Troubleshooting, Warning Messages	If lot lockout is enabled, a patient pouch run will not initiate if passing positive and negative QC has not been performed for the pouch lot.	Potential delay or loss of patient sample test results.	Perform QC tests when new pouch lots are received.
Process Controls	• Refer to the Instructions for Use for details regarding interpreting and monitoring control assay results. • Both control assays must be positive for the test run to pass. If the controls fail, the sample should be retested using a new pouch.	Instructions for Use, Quality Control: Internal Process Controls and Table 7. Interpretation of Controls Field on the SPOTFIRE R, SPOTFIRE R Panel Mini, or SPOTFIRE R/ST Panel Test Report	Risk that operator fails to repeat test if result is invalid.	No test result obtained	

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6. Example Risk Analysis-Post-Analytical Phase

Phase of Testing: Post-Analytical					
Risk Assessment Component: Test System					
Risk Assessment Subcomponent	**Manufacturer's Recommendations and Precautions**	**Source of Manufacturer's Information**	**Possible Error (s)**	**Possible Risk due to Error**	**How can errors or risks be reduced?**
Pouch Removal	If liquid is observed on the exterior of a pouch, the liquid and pouch should be immediately contained and discarded in a biohazard container. The instrument and workspace must be decontaminated as described in the SPOTFIRE® Instrument Operator's Manual. DO NOT PERFORM ADDITIONAL TESTING UNTIL THE AREA HAS BEEN DECONTAMINATED.	Instructions for Use, Laboratory Precautions; System Operator Manual, Precautions when working with the SPOTFIRE System: Decontamination and Cleaning Procedures	Increased risk of instrument and workspace contamination with pouch leak.	Risk of false positive test result.	
Data Interpretation	Refer to Instructions for Use or Quick Guide for a detailed explanation of test report interpretation.	Instructions for Use, Table 4: Interpretation of Results; and Quick Guide Table 1: Interpretation of Results	Risk of reporting incorrect test result.	Risk of reporting incorrect patient test result.	
Run Details Summary	Interpretation of Internal Process Controls: • Pass: Report the results provided on the test report. • Fail: The specimen will need to be retested with a new pouch. • Invalid: The controls are invalid because the run did not complete. (Typically, this indicates a software or hardware error). Follow on-screen instructions. If the failure persists, contact your local bioMérieux subsidiary or distributor.	Instructions for Use, Interpretation of Results, Run Details Summary, Table 7: Interpretation of Controls Field on the SPOTFIRE Panel Test Report; and Quick Guide Table 1: Interpretation of Results: Invalid Results	Risk of failing to repeat test if controls fail or test run is incomplete.	No test results obtained.	
Patient Result Summary	The Result Summary section of the test report lists the overall results of the test. An Action Bar will appear underneath the test results only when further action is necessary. • **NEGATIVE:** Report the Results • **POSITIVE**: [Organism name(s)]: Report results.	Instructions for Use, Interpretation of Results, Table 4; and Quick Guide Table 1: Interpretation of Results: Patient Results	Risk that test results are not reported.	Incorrect patient test result.	

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6. Example Risk Analysis-Post-Analytical Phase continued

Phase of Testing: Post-Analytical					
Risk Assessment Component: Test System					
Risk Assessment Subcomponent	**Manufacturer's Recommendations and Precautions**	**Source of Manufacturer's Information**	**Possible Error (s)**	**Possible Risk due to Error**	**How can errors or risks be reduced?**
Patient Result Summary	• **POSITIVE: Multiple Organisms (4+)**: Detection of four or more organisms is possible but rare. If contamination is suspected, clean the area and retest the sample, then report the results of the retest. If additional guidance is needed, contact your local bioMérieux subsidiary or distributor.	Instructions for Use, Interpretation of Results, Table 4; and Quick Guide Table 1: Interpretation of Results: Patient Results	Operator failure to clean the area and retest the patient sample increases the risk of erroneous test results.	Incorrect patient test result.	
	• **UNCERTAIN: Influenza A Virus**: **Retest the sample ONCE** and report the results of the retest.		Operator failure to retest the patient sample and report the test results increases the risk of erroneous test results.		
	POSITIVE: Influenza A Virus (no subtype identified): Uncommon result, retest ONCE. (SPOTFIRE R Panel and SPOTFIRE R/ST Panels) If the retest provides the same results, contact the appropriate public health authorities for confirmatory testing.		Operator failure to retest the patient sample ONCE and follow guidance in the Quick Guide/ Instructions for Use increases the risk of incorrect test results.		
	• **POSITIVE: Influenza A Virus (multiple subtypes)** **Influenza B Virus** (SPOTFIRE R Panel and SPOTFIRE R/ST Panels): Detection of multiple Influenza infections is possible but rare. This result could be caused by recent FluMist® nasal vaccination or environmental contamination with an Influenza vaccine.		Operator failure to clean the area and retest the patient sample increases the risk of incorrect test results.		
	If contamination is suspected, clean the area (refer to Laboratory Precautions section) and retest the sample, then report the results of the retest.				
	If additional guidance is needed, contact your local bioMérieux subsidiary or distributor.				

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6. Example Risk Analysis-Post-Analytical Phase continued

Phase of Testing: Post-Analytical					
Risk Assessment Component: Test System					
Risk Assessment Subcomponent	**Manufacturer's Recommendations and Precautions**	**Source of Manufacturer's Information**	**Possible Error (s)**	**Possible Risk due to Error**	**How can errors or risks be reduced?**
QC Results Summary	• **Pass:** Report the results.	Instructions for Use, Interpretation of Results, Table 5: Interpretation of QC Results; and Quick Guide Table 1: Interpretation of Results: QC Results	Risk that results are not reported.	Risk of incorrect QC test results.	
	• **Fail:** A Positive QC Test has negative results. Retest the Positive QC material ONCE. If the failure persists, contact your local bioMérieux subsidiary or distributor for further instruction.		Operator failure to retest the QC material ONCE and follow guidance in Quick Guide/ Instructions for Use increases the risk of incorrect QC test results.		
	• **Fail:** A Negative QC Test has positive results. If contamination is suspected, clean the area according to instructions on p.1 of the Quick Guide and retest using a new Negative QC vial. If the failure persists, contact your local bioMérieux subsidiary or distributor for further instruction.		Operator failure to clean the area and retest the QC material increases the risk of incorrect QC test results.		
Data Management	The laboratory must have an adequate manual or electronic system(s) in place to ensure test results and other patient-specific data are accurately and reliably sent from the point of data entry (whether interfaced or entered manually) to final report destination, in a timely manner.	CMS, Appendix C 42CFR §493.1291(a)	Increased risk of transcriptional error and increased risk of reporting incorrect patient test results.	Risk of incorrect test results.	
	The regulations apply to manual as well as automated record systems (e.g., a laboratory information system or LIS). Regardless of the means used to transmit laboratory results, routine checks should be conducted to verify that transmissions are being accurately and reliably conveyed to the final report destination.				
	If a Laboratory Information System is implemented- auto verification or other confirmatory testing must be performed using the guidelines set by the regulatory body governing your laboratory.	CMS, Appendix C 42CFR §493.1291 and CAP 2024 Laboratory General Checklist			

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6. Example Risk Analysis-Post-Analytical Phase continued

Phase of Testing: Post-Analytical					
Risk Assessment Component: Environment					
Risk Assessment Subcomponent	**Manufacturer's Recommendations and Precautions**	**Source of Manufacturer's Information**	**Possible Error (s)**	**Possible Risk due to Error**	**How can errors or risks be reduced?**
Preventing Organism Contamination	Refer to Instructions for Use for guidelines on preventing organism contamination:	Instructions for Use, Laboratory Precautions	Risk of erroneous false positive test results obtained and reported due to contamination of the environment with organism.	Risk of false positive test results.	
	• Personnel collecting and/or testing specimens may carry or shed common respiratory pathogens asymptomatically and can inadvertently contaminate the specimen while it is being processed. Careful adherence to the sample processing steps described in this document is recommended to avoid possible contamination. Samples may be processed in a clean biosafety cabinet (if available) or according to local/laboratory guidelines. If a biosafety cabinet is not used, a dead air box (e.g., AirClean PCR workstation), a splash shield (e.g., Bel-Art Scienceware Splash Shields), or a face shield may be used when preparing samples.				
	• Personnel with active respiratory symptoms (runny nose, cough) should wear a standard surgical mask (or equivalent) and should avoid touching the mask while handling specimens.				
	• It is recommended to avoid handling specimens or pouches in an area used to routinely process respiratory pathogen culture, and/or immunofluorescence testing, unless the area is thoroughly cleaned first.				
	• Prior to processing specimens, thoroughly clean both the work area and the BIOFIRE® Pouch Loading Station using a suitable cleaner such as freshly prepared 10% bleach or a similar disinfectant. To avoid residue build-up and potential damage to the specimen or interference from disinfectants, wipe disinfected surfaces with water.	Instructions for Use, Laboratory Precautions; Quick Guide: Contamination Precautions			
	• Specimens and pouches should be handled and/or tested one-at-a-time. Always change gloves and clean the work area between each pouch and specimen.				

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6. Example Risk Analysis-Post-Analytical Phase continued

Phase of Testing: Post-Analytical					
Risk Assessment Component: Environment					
Risk Assessment Subcomponent	**Manufacturer's Recommendations and Precautions**	**Source of Manufacturer's Information**	**Possible Error (s)**	**Possible Risk due to Error**	**How can errors or risks be reduced?**
Preventing Organism Contamination	• Use clean gloves when removing Sample Buffer ampoules and Sample/Hydration Injection Vials from the SPRK package. • Avoid collecting or handling specimens in areas that are exposed to vaccine material for pathogens detected by the SPOTFIRE R Panel, the SPOTFIRE R Panel Mini, the SPOTFIRE R/ST Panel, or the SPOTFIRE R/ST Panel Mini (e.g. influenza, SARS-CoV-2, *Bordetella pertussis*, and poliovirus (Human Rhinovirus/Enterovirus)). Vaccines may contain PCR-detectable DNA or RNA. If possible, particular care should be taken to avoid contamination of the specimen or testing areas (especially with nasal spray vaccines such as FluMist® and *B. pertussis* acellular vaccines such as Pentacel®, Daptacel®, and Adacel®; http://www.cdc.gov/pertussis/clinical/diagnostic-testing/diagnosis-pcr-bestpractices.html). Contamination of specimens or testing materials with vaccine can cause false-positive results.	Instructions for Use, Laboratory Precautions	Risk of erroneous false positive test results obtained and reported due to contamination of the environment with organism.	Risk of false positive test results.	
Preventing Amplicon Contamination	Refer to Instructions for Use for guidelines on preventing amplicon contamination: • Discard used pouches in a biohazard container immediately after the run has completed. • Avoid excessive handling of pouches after test runs. • Change gloves after handling a used pouch. • Avoid exposing pouches to sharp edges or anything that might cause a puncture.	Instructions for Use, Laboratory Precautions; Quick Guide: Contamination Precautions	Risk of erroneous false positive test results caused by contamination of the work area with PCR amplicon.	Risk of false positive test results.	

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7. Additional IQCP Resources

Laboratories may consult the following publicly available resources when developing their IQCP.

- American Society for Microbiology-Molecular IQCP Template
  https://asm.org/Protocols/Individualized-Quality-Control-Plan-IQCP
- The Centers for Disease Control and Prevention: Individualized Quality Control Plan (IQCP)
  https://www.cdc.gov/lab-quality/php/iqcp/index.html
- Centers for Medicare and Medicaid Services: Individualized Quality Control Plan (IQCP)
  https://www.cms.gov/medicare/quality/clinical-laboratory-improvement-amendments/quality-control
- The College of American Pathologists IQCP FAQ
  https://documents.cap.org/documents/iqcp-faqs.pdf
- The College of American Pathologist All Common Checklist, 2024 Edition
- The Clinical and Laboratory Standards Institute Laboratory Quality Control Based on Risk Management (EP23-A)

Technical Support Contact Information

bioMérieux is dedicated to providing the best customer support available. If you have questions or concerns about this process, please contact your local bioMérieux representative or your authorized distributor.

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