

BIOFIRE® SPOTFIRE® CONNECTIVITY SOFTWARE MAPPING GUIDE

BIOFIRE® SPOTFIRE® System



TABLE OF CONTENTS

Do	cumer	nt Revision History	3
1.	Using	g this Document	4
	1.1.	Purpose	4
	1.2.	Interface Overview	4
	1.3.	Mapping by Pouch Type	4
	1.4.	Interpreting the Table Headers	6
2.	BIOF	IRE® SPOTFIRE® Respiratory Panel Pouch	7
	2.1.	SPOTFIRE Respiratory Panel Disposable (Pouch)	7
	2.2.	SPOTFIRE Respiratory Panel Universal Order/Service ID (Panel)	7
	2.3.	SPOTFIRE Respiratory Panel Associated Sample Type(s)	7
	2.4.	SPOTFIRE Respiratory Panel Possible Panel Results	7
	2.5.	SPOTFIRE Respiratory Panel Possible Panel Observations	8
	2.6.	SPOTFIRE Respiratory Panel Observation Conditional Reporting	13
	2.7.	SPOTFIRE Respiratory Panel Warnings and Notes	14
3.	BIOF	IRE® SPOTFIRE® Respiratory Panel Mini Pouch	15
	3.1.	SPOTFIRE Respiratory Panel Mini Disposable (Pouch)	15
	3.2.	SPOTFIRE Respiratory Panel Mini Universal Order/Service ID (Panel)	15
	3.3.	SPOTFIRE Respiratory Panel Mini Associated Sample Type(s)	15
	3.4.	SPOTFIRE Respiratory Panel Mini Possible Panel Results	15
	3.5.	SPOTFIRE Respiratory Panel Mini Possible Panel Observations	16
	3.6.	SPOTFIRE Respiratory Panel Mini Observation Conditional Reporting	20
	3.7.	SPOTFIRE Respiratory Panel Mini Warnings and Notes	21
4.	BIOF	IRE [®] SPOTFIRE [®] Respiratory/Sore Throat Panel Pouch	22
	4.1.	SPOTFIRE Respiratory/Sore Throat Panel Disposable (Pouch)	22
	4.2.	SPOTFIRE Respiratory/Sore Throat Panel Universal Order/Service ID (Panel)	22
	4.3.	SPOTFIRE Respiratory/Sore Throat Panel Associated Sample Type(s)	22
	4.4.	SPOTFIRE Respiratory/Sore Throat Panel Possible Panel Results	23
	4.5.	SPOTFIRE Respiratory/Sore Throat Panel Possible Panel Observations	23
	4.6.	SPOTFIRE Respiratory/Sore Throat Panel Observation Conditional Reporting	30
	4.7.	SPOTFIRE Respiratory/Sore Throat Panel Warnings and Notes	31
5.	Tech	nical Support Contact Information	32

Document Revision History

Document Number	Revision Description	Release Date
BFR0001-9777-01	Initial release of the document.	04/2023
BFR0001-9777-02	Added Respiratory Panel Mini	06/2023
BFR0001-9777-03	Added Respiratory/Sore Throat	09/2023
BFR0001-9777-04	Corrected Universal Order/Service ID information for Respiratory Panel Mini	10/2023
	Added warning that the Respiratory Menu (on R/ST) Universal Order/Service ID will change pending FDA feedback	

1. Using this Document

1.1. Purpose

The purpose of this document is to provide details on how information obtained from sample testing using a BIOFIRE® SPOTFIRE® Pouch (referred to as a SPOTFIRE Pouch throughout this document) is electronically reported to a connected information system using the BIOFIRE® SPOTFIRE® Connectivity Software (referred to as SPOTFIRE Connectivity Software throughout this document). This document details codes applicable to all currently released BIOFIRE® SPOTFIRE® IVD tests, applicable to both patient and QC sample testing, as relevant to the interface type supported.

1.2. Interface Overview

As a plug-in to the system, the SPOTFIRE Connectivity Software provides the BIOFIRE[®] SPOTFIRE[®] System (referred to as SPOTFIRE System throughout this document) with the ability to interface with a data manager (e.g., middleware) to electronically transfer test information. There is one supported implementation:

1. A bidirectional transfer of structured data sets from the SPOTFIRE System to a data manager utilizing the POCT01-A2 standard, referred to as the POCT interface throughout this document.

1.3. Mapping by Pouch Type

A SPOTFIRE Pouch is a disposable testing pack allowing for sample testing on a specific BIOFIRE[®] SPOTFIRE[®] Panel(s) (referred to as a SPOTFIRE Panel throughout this document). Each SPOTFIRE Panel is associated with a unique universal order/service identifier, a unique set of observations and results, and is cleared for use with a specific sample type(s).

The unique information associated with each currently released SPOTFIRE Pouch can be found in the corresponding section for that pouch within this document. For each currently released pouch, the following information is provided within the section:

- Subsection 1 provides the name of the associated disposable testing pack (SPOTFIRE Pouch).
- Subsection 2 provides the universal ID order/service codes for the associated SPOTFIRE Panel(s) on the pouch.
- Subsection 3 provides the unique sample type(s) the SPOTFIRE Pouch is cleared for use with.
- Subsection 4 provides the possible results that may be associated with each observation on the SPOTFIRE Panel(s). Each result is associated with a result number, which is used to indicate if that result is a possible result for the specific observations on the SPOTFIRE Panel(s) (detailed in subsections 5 and 6).

For reference, all possible results and their corresponding result numbers are provided in Table 1.3.1. Note that not every possible result may be used by a SPOTFIRE Pouch. Users should refer to subsections 5 and 6 for the respective SPOTFIRE Pouch to see which possible results the observations on a SPOTFIRE Pouch may be associated with.

Qualitative Results Coding System: BMX				
Code	Display Name	Result Number		
POS	Positive	1		
NEG	Negative	2		
UNCERT	Uncertain	3		
PASS	Pass	100		
FAIL	Fail	101		
INVALID	Invalid	102		
INV_CF	Invalid Internal Process Control Failure	200		
INV_AB	Invalid Aborted Run	201		
INV_SE	Invalid Software Error	202		
INV_IE	Invalid Instrument Error	203		
INV_RI	Invalid Run Incomplete	204		
INV_OC	Invalid Operational Conditions Out of Range	205		
Quantitative Results Coding system: UCUM				
	Result Number			
71.52 Cel^DegreeCels Note: 71.52 is displaye the system.	71.52 Cel^DegreeCelsius 300 Note: 71.52 is displayed for example purposes only. This value will be populated with data from the system. 300			

Table 1.3.1: All Possible Observation Results

- Subsection 5 provides all of the possible observations for the SPOTFIRE Panel(s), for both Patient and QC designated runs, and which possible results each observation can be associated with. This includes observations of the following type, as applicable:
 - **Run Status**: An observation used to inform the status (success or failure) of the panel test.
 - **QC Result**: An observation used to inform the overall result (e.g., pass, fail) of the positive or negative QC sample.
 - **Controls**: Observations with an expected result to ensure the disposable pouch is not compromised (e.g., PCR2 control, RNA process control). Failure to obtain the expected result for either control will cause the test to be invalidated.
 - **Targets:** The pathogens that the sample is being tested for.
- Subsection 6 provides any conditional reporting rules that may apply to the observations on the panel(s).
- Subsection 7 includes any notes that are associated with each SPOTFIRE Panel, for both Patient and QC designated runs. Each panel may be associated with warnings or notes that give additional information to help with interpretation of information on the report or indicate relevant actions a user should take.

1.4. Interpreting the Table Headers

Throughout this document, tables are used to indicate the properties for the information described in section 1.3. The types of header information that are used and their meanings are:

- Code: A unique string used to identify the property
- **Display Name:** A string used to identify the full name of the property, correlating to the code, as displayed in the BIOFIRE[®] SPOTFIRE[®] Software
- Coding System: The scheme used to define the codes used
- Result Number: An identifier assigned to a specific result type
- Reporting Condition: Rules describing when properties are applicable
- Comment: A note, warning, or action that may be associated with the test

Note that throughout this document, a grayed-out cell means that the particular property is not applicable/supported or will require further interpretation (as noted in the cell).

The first column of each table is color-coded based on the corresponding SPOTFIRE Panel to improve readability, as follows:

Color	Panel Name		
	Respiratory Panel		
	Respiratory Panel Mini		
	Respiratory/Sore Throat Panel		

2. BIOFIRE® SPOTFIRE® Respiratory Panel Pouch

The BIOFIRE® SPOTFIRE® Respiratory Panel (referred to as the SPOTFIRE R Panel), run using a SPOTFIRE R Panel pouch, is used to detect and discriminate upper respiratory pathogens in samples from individuals with signs or symptoms of upper respiratory tract infections.

An electronic report for the SPOTFIRE R Panel contains information from a single test run using a SPOTFIRE R Panel pouch.

2.1. SPOTFIRE Respiratory Panel Disposable (Pouch)

The SPOTFIRE R Panel is run using a pouch as the disposable, whose properties are indicated in Table 2.1.1.

Table 2.1.1: Disposable (Pouch)

Name	Coding System
R Panel	BMX

2.2. SPOTFIRE Respiratory Panel Universal Order/Service ID (Panel)

The SPOTFIRE R Panel pouch is used to test for a panel, which is a syndromic test comprised of multiple pathogens.

The panel (or test) properties are indicated in Table 2.2.1.

Table 2.2.1: Universal Order/Service ID (Panel)

Code	Display Name	Coding System
R	Respiratory Panel	BMX

2.3. SPOTFIRE Respiratory Panel Associated Sample Type(s)

The SPOTFIRE R Panel pouch may be used with a subset of cleared sample type(s), whose properties are indicated in Table 2.3.1.

Table 2.3.1: Associated Sample Type(s)

Code	Display Name	Coding System
NPS	Nasopharyngeal Swab	BMX

2.4. SPOTFIRE Respiratory Panel Possible Panel Results

The possible results (derived from Table 1.3.1) for the SPOTFIRE R Panel are indicated in Table 2.4.1. Note that not every result in Table 2.4.1 will be associated with all of the SPOTFIRE R Panel observations. Refer to sections 2.5 and 2.6 to see which of the possible results each observation on the panel may be associated with.

Qualitative Results Coding System: BMX				
Code	Display Name	Result Number		
POS	Positive	1		
NEG	Negative	2		
UNCERT	Uncertain	3		
PASS	Pass	100		
FAIL	Fail	101		
INVALID	Invalid	102		
INV_CF	Invalid Internal Process Control Failure	200		
INV_AB	Invalid Aborted Run	201		
INV_SE	Invalid Software Error	202		
INV_IE	Invalid Instrument Error	203		
INV_RI	Invalid Run Incomplete	204		
INV_OC	Invalid Operational Conditions Out of Range	205		
Quantitative Results Coding system: UCUM				
71.52 Cel^DegreeCelsius 300 Note: 71.52 is displayed for example purposes only. This value will be populated with data from the system. 300				

2.5. SPOTFIRE Respiratory Panel Possible Panel Observations

The SPOTFIRE R Panel tests for a set of observations based on a specific syndrome. The observations on the SPOTFIRE R Panel and their properties are indicated in:

- Table 2.5.1: Patient Designated Tests
- Table 2.5.2: QC Designated Tests

	Run Status Observations Coding system: BMX			
	Code	Display Name	Possible Result Number(s) (from Table 2.4.1)	Possible Result Code(s) (from Table 2.4.1)
		Run Status	100	PASS
			200	INV_CF
			201	INV_AB
	RUN_STAT		202	INV_SE
			203	INV_IE
			204	INV_RI
			205	INV_OC

Table 2.5.1: Panel Observations for Patient Designated Tests

Target Observations Coding System: BMX	rget Observations Iding System: BMX			
Code	Display Name	Possible Result Number(s) (from Table 2.4.1)	Possible Result Code(s) (from Table 2.4.1)	
RPx01001	Adenovirus	1	POS	
		2	NEG	
RPx02001	Bordetella parapertussis	1	POS	
		2	NEG	
RPx02002	Bordetella pertussis	1	POS	
		2	NEG	
RPx02003	Chlamydia pneumoniae	1	POS	
		2	NEG	
RPx01002	Coronavirus SARS-CoV-2	1	POS	
		2	NEG	
RPx01003	Coronavirus (seasonal)	1	POS	
		2	NEG	
RPx01004	Human metapneumovirus	1	POS	
		2	NEG	
RPx01005	Human rhinovirus/enterovirus	1	POS	
		2	NEG	
	Influenza A virus	1	POS	
RPx01006		2	NEG	
		3	UNCERT	
RPx01007	Influenza A virus A/H1-2009	1	POS	
		2	NEG	
RPx01008	Influenza A virus A/H3	1	POS	
		2	NEG	
RPx01009	Influenza B virus	1	POS	
		2	NEG	
RPx02004	Mycoplasma pneumoniae	1	POS	
11 X02004		2	NEG	
RPx01010	Parainfluenza virus	1	POS	
		2	NEG	
RPx01011	Respiratory syncytial virus	1	POS	
		2	NEG	
Control Observations Coding System: BMX				

Code	Display Name	Possible Result Number(s) (from Table 2.4.1)	Possible Result Code(s) (from Table 2.4.1)
	PCP2 Control	100	PASS
FORZ_OTTL		101	FAIL
PCR2C_TM_A	PCR2 Control Tm Value A	300	Quantitative (variable) *see section 2.6 for conditional reporting of this observation
PCR2C_TM_B	PCR2 Control Tm Value B	300	Quantitative (variable) *see section 2.6 for conditional reporting of this observation
PCR2C_TM_C	PCR2 Control Tm Value C	300	Quantitative (variable) *see section 2.6 for conditional reporting of this observation
	RNA Process Control	100	PASS
RNA_CIRL		101	FAIL
RNAC_TM_A	RNA Process Control Tm Value A	300	Quantitative (variable) *see section 2.6 for conditional reporting of this observation
RNAC_TM_B	RNA Process Control Tm Value B	300	Quantitative (variable) *see section 2.6 for conditional reporting of this observation
RNAC_TM_C	RNA Process Control Tm Value C	300	Quantitative (variable) *see section 2.6 for conditional reporting of this observation

Table 2.5.2: Panel Observations for QC Designated Tests

	Run Status Observations Coding system: BMX			
	Code	Display Name	Possible Result Number(s) (from Table 2.4.1)	Possible Result Code(s) (from Table 2.4.1)
		Run Status	100	PASS
			200	INV_CF
			201	INV_AB
	RUN_STAT		202	INV_SE
			203	INV_IE
			204	INV_RI
			205	INV_OC

QC Result Observations Coding system: BMX				
Code		Display Name	Possible Result Number(s) (from Table 2.4.1)	Possible Result Code(s) (from Table 2.4.1)
			100	PASS
QC_RSLT		QC Result	101	FAIL
			102	INVALID
Target Obs Coding Syst	ervations tem: BMX			
Code		Display Name	Possible Result Number(s) (from Table 2.4.1)	Possible Result Code(s) (from Table 2.4.1)
PPv01001		Adopovirus	1	POS
KFX01001		Adenovirus	2	NEG
PPv02001		Rordotolla paraportussis	1	POS
KF X02001		Bordetella parapertussis	2	NEG
RPv02002	PDv02002	Bordetella pertussis	1	POS
111 X02002			2	NEG
RPx02003			1	POS
			2	NEG
RPx01002		Coronavirus SARS-CoV-2	1	POS
			2	NEG
RPx01003		Coronavirus (seasonal)	1	POS
			2	NEG
RPx01004		Human metapneumovirus	1	POS
			2	NEG
RPx01005		Human rhinovirus/enterovirus	1	POS
			2	NEG
RPx01006		Influenza A virus	1	POS
			2	NEG
RPx01007		Influenza A virus A/H1-2009	1	POS
			2	NEG
RPx01008		Influenza A virus A/H3	1	POS
			2	NEG
RPx01009		Influenza B virus	1	POS
11 101003			2	NEG
RPx02004		Mycoplasma pneumoniae	1	POS

		2	NEG
PDv01010	Poreinfluenze virue	1	POS
RPX01010	Paraimiuenza virus	2	NEG
PDv01011	Poopiratory expectiel virue	1	POS
		2	NEG
Control Observations Coding System: BMX			
Code	Display Name	Possible Result Number(s) (from Table 2.4.1)	Possible Result Code(s) (from Table 2.4.1)
	DCD2 Control	100	PASS
PGR2_GTRL	PCR2 Control	101	FAIL
PCR2C_TM_A	PCR2 Control Tm Value A	300	Quantitative (variable) *see section 2.6 for conditional reporting of this observation
PCR2C_TM_B	PCR2 Control Tm Value B	300	Quantitative (variable) *see section 2.6 for conditional reporting of this observation
PCR2C_TM_C	PCR2 Control Tm Value C	300	Quantitative (variable) *see section 2.6 for conditional reporting of this observation
	PNA Process Control	100	PASS
	KNA FICESS CONTO	101	FAIL
RNAC_TM_A	RNA Process Control Tm Value A	300	Quantitative (variable) *see section 2.6 for conditional reporting of this observation
RNAC_TM_B	RNA Process Control Tm Value B	300	Quantitative (variable) *see section 2.6 for conditional reporting of this observation
RNAC_TM_C	RNA Process Control Tm Value C	300	Quantitative (variable) *see section 2.6 for conditional reporting of this observation

2.6. SPOTFIRE Respiratory Panel Observation Conditional Reporting

Some observations on the SPOTFIRE R Panel are conditionally reported on the electronic report, as indicated in section 2.5. The reporting conditions for conditionally reported observations on the SPOTFIRE R Panel are indicated in Table 2.6.1.

Table	2.6.1:	Conditional	Reporting
		••••••••	

Observation Display Name (from Table 2.5.1 and/or 2.5.2)	Result Display Name (from Table 2.4.1)	Reporting Condition
PCR2 Control Tm Value A PCR2 Control Tm Value B PCR2 Control Tm Value C	Quantitative (variable)	An observation is included in the electronic report for each Control pouch well for which a Tm value was found. Note that A, B, and C correlate directly to a specific well on the pouch array. e.g., if two Tm values are found for the PCR2 control, only two of the three observations will be sent
		Otherwise, the observation is not included in the electronic report.
RNA Process Control Tm Value A RNA Process Control Tm Value B RNA Process Control Tm Value C	Quantitative (variable)	An observation is included in the electronic report for each Control pouch well for which a Tm value was found. Note that A, B, and C correlate directly to a specific well on the pouch array. e.g., if two Tm values are found for the PCR2 control, only two of the three observations will be sent
		Otherwise, the observation is not included in the electronic report.

2.7. SPOTFIRE Respiratory Panel Warnings and Notes

The SPOTFIRE R Panel is associated with warnings or notes that give additional information to help with interpretation of the information on the report, as indicated in Table 2.7.1.

Table 2.7.1: Test Notes

Patient Designated Test			
Comment	Reporting Condition		
Action: This result is uncommon. Consult the Interpretation of Results table in Quick Guide.	 Present when any of the following apply for a run: 4+ organisms have positive results an organism(s) has an uncertain result Influenza A virus has a positive result, Influenza A virus A/H1-2009 and Influenza A virus A/H3 both have negative results all Influenza A and B strains have positive results 		
Action: Retest once. If problem persists, contact bioMérieux Customer Support.	Present when the internal pouch controls fail.		
PCR Test	Always present.		
Edit History: Sample ID changed from {0} to {1} by {2} ({3}) at {4} *{0} is original sampleID, {1} is new sampleID, {2} is Firstname Lastname of the operator who made the change, {3} is operatorID of the operator who made the change, and {4} is DateTime of the change.	Present when an operator changes a sample ID after the test finished, and manually resent the run up to the connected information system.		
QC Designated Test			
Comment	Reporting Condition		
Action: Consult the Interpretation of Results table in Quick Guide.	Present when a run has a QC Result of Fail.		
Action: Retest once. If problem persists, contact bioMérieux Customer Support.	Present when the internal pouch controls fail.		
PCR Test	Always present.		

3. BIOFIRE® SPOTFIRE® Respiratory Panel Mini Pouch

The BIOFIRE® SPOTFIRE® Respiratory Panel Mini (referred to as the SPOTFIRE R Panel Mini), run using a SPOTFIRE R Panel Mini pouch, is used to detect and discriminate upper respiratory pathogens in samples from individuals with signs or symptoms of upper respiratory tract infections.

An electronic report for the SPOTFIRE R Panel Mini contains information from a single test run using a SPOTFIRE R Panel Mini pouch.

3.1. SPOTFIRE Respiratory Panel Mini Disposable (Pouch)

The SPOTFIRE R Panel Mini is run using a pouch as the disposable, whose properties are indicated in Table 3.1.1.

Table 3.1.1: Disposable (Pouch)

Name	Coding System
R Panel Mini	BMX

3.2. SPOTFIRE Respiratory Panel Mini Universal Order/Service ID (Panel)

The SPOTFIRE R Panel Mini pouch is used to test for a panel, which is a syndromic test comprised of multiple pathogens.

The panel (or test) properties are indicated in Table 3.2.1.

Table 3.2.1: Universal Order/Service ID (Panel)

Code	Display Name	Coding System
RM	Respiratory Panel Mini	BMX

3.3. SPOTFIRE Respiratory Panel Mini Associated Sample Type(s)

The SPOTFIRE R Panel Mini pouch may be used with a subset of cleared sample type(s), whose properties are indicated in Table 3.3.1.

Table 3.3.1: Associated Sample Type(s)

Code	Display Name	Coding System
NPS	Nasopharyngeal Swab	BMX

3.4. SPOTFIRE Respiratory Panel Mini Possible Panel Results

The possible results (derived from Table 1.3.1) for the SPOTFIRE R Panel Mini are indicated in Table 3.4.1. Note that not every result in Table 3.4.1 will be associated with all of the SPOTFIRE R Panel Mini observations. Refer to sections 3.5 and 3.6 to see which of the possible results each observation on the panel may be associated with.

Qualitative Results Coding System: BMX					
Code	Display Name	Result Number			
POS	Positive	1			
NEG	Negative	2			
UNCERT	Uncertain	3			
PASS	Pass	100			
FAIL	Fail	101			
INVALID	Invalid	102			
INV_CF	Invalid Internal Process Control Failure	200			
INV_AB	Invalid Aborted Run	201			
INV_SE	Invalid Software Error	202			
INV_IE	Invalid Instrument Error	203			
INV_RI	Invalid Run Incomplete	204			
INV_OC	Invalid Operational Conditions Out of Range	205			
Quantitative Results Coding system: UCUM					
71.52 Cel^DegreeCelsius Note: 71.52 is displayed for example purposes only. This value will be populated with data from the system.					

Table 3.4.1: Possible Panel Results

3.5. SPOTFIRE Respiratory Panel Mini Possible Panel Observations

The SPOTFIRE R Panel Mini tests for a set of observations based on a specific syndrome. The observations on the SPOTFIRE R Panel Mini and their properties are indicated in:

- Table 3.5.1: Patient Designated Tests
- Table 3.5.2: QC Designated Tests

Table 3.5.1: Panel Observations for Patient Designated Tests

	Run Status Observations Coding system: BMX					
	Code	Display Name	Possible Result Number(s) (from Table 2.4.1)	Possible Result Code(s) (from Table 2.4.1)		
	RUN_STAT	Run Status	100	PASS		
			200	INV_CF		
			201	INV_AB		
			202	INV_SE		
			203	INV_IE		

		204	INV_RI		
		205	INV_OC		
Target Observations Coding System: BMX					
Code	Display Name	Possible Result Number(s) (from Table 3.4.1)	Possible Result Code(s) (from Table 3.4.1)		
RMN×01001	Coronavirus SARS-CoV-2	1	POS		
		2	NEG		
RMNx01002	Human rhinovirus	1	POS		
	Human minoviras	2	NEG		
		1	POS		
RMNx01003	Influenza A virus	2	NEG		
		3	UNCERT		
	Influenza B virus	1	POS		
110111004		2	NEG		
	Pospiratory synovital virus	1	POS		
RIVINXU1005	Respiratory syncytial virus	2	NEG		
Control Observations Coding System: BMX					
Code	Display Name	Possible Result Number(s) (from Table 3.4.1)	Possible Result Code(s) (from Table 3.4.1)		
Code	Display Name	Possible Result Number(s) (from Table 3.4.1) 100	Possible Result Code(s) (from Table 3.4.1) PASS		
Code PCR2_CTRL	Display Name PCR2 Control	Possible Result Number(s) (from Table 3.4.1) 100 101	Possible Result Code(s) (from Table 3.4.1) PASS FAIL		
Code PCR2_CTRL PCR2C_TM_A	Display Name PCR2 Control PCR2 Control Tm Value A	Possible Result Number(s) (from Table 3.4.1)100101300	Possible Result Code(s) (from Table 3.4.1) PASS FAIL Quantitative (variable) *see section 3.6 for conditional reporting of this observation		
Code PCR2_CTRL PCR2C_TM_A PCR2C_TM_B	Display Name PCR2 Control PCR2 Control Tm Value A PCR2 Control Tm Value B	Possible Result Number(s) (from Table 3.4.1)100101300300	Possible Result Code(s) (from Table 3.4.1) PASS FAIL Quantitative (variable) *see section 3.6 for conditional reporting of this observation Quantitative (variable) *see section 3.6 for conditional reporting of this observation Quantitative (variable) *see section 3.6 for conditional reporting of this observation		
Code PCR2_CTRL PCR2C_TM_A PCR2C_TM_B PCR2C_TM_C	Display Name PCR2 Control PCR2 Control Tm Value A PCR2 Control Tm Value B PCR2 Control Tm Value C	Possible Result Number(s) (from Table 3.4.1)100101300300300	Possible Result Code(s) (from Table 3.4.1) PASS FAIL Quantitative (variable) *see section 3.6 for conditional reporting of this observation Quantitative (variable) *see section 3.6 for conditional reporting of this observation Quantitative (variable) *see section 3.6 for conditional reporting of this observation Quantitative (variable) *see section 3.6 for conditional reporting of this observation		
Code PCR2_CTRL PCR2C_TM_A PCR2C_TM_B PCR2C_TM_C RNA_CTRL	Display Name PCR2 Control PCR2 Control Tm Value A PCR2 Control Tm Value B PCR2 Control Tm Value C RNA Process Control	Possible Result Number(s) (from Table 3.4.1) 100 101 300 300 300 100	Possible Result Code(s) (from Table 3.4.1) PASS FAIL Quantitative (variable) *see section 3.6 for conditional reporting of this observation Quantitative (variable) *see section 3.6 for conditional reporting of this observation Quantitative (variable) *see section 3.6 for conditional reporting of this observation Quantitative (variable) *see section 3.6 for conditional reporting of this observation PASS		
Code PCR2_CTRL PCR2C_TM_A PCR2C_TM_B PCR2C_TM_C RNA_CTRL	Display Name PCR2 Control PCR2 Control Tm Value A PCR2 Control Tm Value B PCR2 Control Tm Value C RNA Process Control	Possible Result Number(s) (from Table 3.4.1) 100 300 300 300 100 101	Possible Result Code(s) (from Table 3.4.1)PASSFAILQuantitative (variable) *see section 3.6 for conditional reporting of this observationQuantitative (variable) *see section 3.6 for conditional reporting of this observationPASSFAIL		
Code PCR2_CTRL PCR2C_TM_A PCR2C_TM_B PCR2C_TM_C RNA_CTRL RNAC_TM_A	Display Name PCR2 Control PCR2 Control Tm Value A PCR2 Control Tm Value B PCR2 Control Tm Value C RNA Process Control RNA Process Control Tm Value A	Possible Result Number(s) (from Table 3.4.1) 100 101 300 300 100 101 300 300 300 300 300 300 300 300 300	Possible Result Code(s) (from Table 3.4.1)PASSFAILQuantitative (variable) *see section 3.6 for conditional reporting of this observationQuantitative (variable) *see section 3.6 for conditional reporting of this observationPASSFAILQuantitative (variable) *see section 3.6 for conditional reporting of this observation		

			Quantitative (variable)
RNAC_TM_C	RNA Process Control Tm Value C	300	*see section 3.6 for conditional
			reporting of this observation

Table 3.5.2: Panel Observations for QC Designated Tests

Run Status Observations Coding system: BMX	3		
Code	Display Name	Possible Result Number(s) (from Table 3.4.1)	Possible Result Code(s) (from Table 3.4.1)
		100	PASS
		200	INV_CF
		201	INV_AB
RUN_STAT	Run Status	202	INV_SE
		203	INV_IE
		204	INV_RI
		205	INV_OC
QC Result Observations Coding system: BMX			
Code	Display Name	Possible Result Number(s) (from Table 3.4.1)	Possible Result Code(s) (from Table 3.4.1)
		100	PASS
QC_RSLT	QC Result	101	FAIL
		102	INVALID
Target Observations Coding System: BMX		· ·	
Code	Display Name	Possible Result Number(s) (from Table 3.4.1)	Possible Result Code(s) (from Table 3.4.1)
DMN 04004		1	POS
KWINXU1UU1	Coronavirus SARS-Cov-2	2	NEG
DMN-04000	Linear address d	1	POS
KMNXU1UU2	Human minovirus	2	NEG
		1	POS
RMNx01003	Influenza A virus	2	NEG
RMNx01004	Influenza B virus	1	POS

		2	NEG
PMNv01005	Poopiratory expecticl virue	1	POS
RIVINXUTUUS	Respiratory syncytial virus	2	NEG
Control Observations Coding System: BMX			
Code	Display Name	Possible Result Number(s) (from Table 3.4.1)	Possible Result Code(s) (from Table 3.4.1)
	DCD2 Control	100	PASS
PGRZ_GTRL	PCR2 Control	101	FAIL
PCR2C_TM_A	PCR2 Control Tm Value A	300	Quantitative (variable) *see section 3.6 for conditional reporting of this observation
PCR2C_TM_B	PCR2 Control Tm Value B	300	Quantitative (variable) *see section 3.6 for conditional reporting of this observation
PCR2C_TM_C	PCR2 Control Tm Value C	300	Quantitative (variable) *see section 3.6 for conditional reporting of this observation
	PNA Process Control	100	PASS
	KINA FIOCESS CONTO	101	FAIL
RNAC_TM_A	RNA Process Control Tm Value A	300	Quantitative (variable) *see section 3.6 for conditional reporting of this observation
RNAC_TM_B	RNA Process Control Tm Value B	300	Quantitative (variable) *see section 3.6 for conditional reporting of this observation
RNAC_TM_C	RNA Process Control Tm Value C	300	Quantitative (variable) *see section 3.6 for conditional reporting of this observation

3.6. SPOTFIRE Respiratory Panel Mini Observation Conditional Reporting

Some observations on the SPOTFIRE R Panel Mini are conditionally reported on the electronic report, as indicated in section 3.5. The reporting conditions for conditionally reported observations on the SPOTFIRE R Panel Mini are indicated in Table 3.6.1.

Table 3.6.1: Conditional Reporting

Observation Display Name (from Table 3.5.1 and/or 3.5.2)	Result Display Name (from Table 3.4.1)	Reporting Condition
PCR2 Control Tm Value A PCR2 Control Tm Value B PCR2 Control Tm Value C	Quantitative (variable)	An observation is included in the electronic report for each Control pouch well for which a Tm value was found. Note that A, B, and C correlate directly to a specific well on the pouch array. e.g., if two Tm values are found for the PCR2 control, only two of the three observations will be sent
		Otherwise, the observation is not included in the electronic report.
RNA Process Control Tm Value A RNA Process Control Tm Value B RNA Process Control Tm Value C	Quantitative (variable)	An observation is included in the electronic report for each Control pouch well for which a Tm value was found. Note that A, B, and C correlate directly to a specific well on the pouch array. e.g., if two Tm values are found for the PCR2 control, only two of the three observations will be sent
		Otherwise, the observation is not included in the electronic report.

3.7. SPOTFIRE Respiratory Panel Mini Warnings and Notes

The SPOTFIRE R Panel Mini is associated with warnings or notes that give additional information to help with interpretation of the information on the report, as indicated in Table 3.7.1.

Table 3.7.1: Test Notes

Patient Designated Test				
Comment	Reporting Condition			
Action: This result is uncommon. Consult the Interpretation of Results table in Quick Guide.	 Present when any of the following apply for a run: 4+ organisms have positive results an organism(s) has an uncertain result 			
Action: Retest once. If problem persists, contact bioMérieux Customer Support.	Present when the internal pouch controls fail.			
PCR Test	Always present.			
Edit History: Sample ID changed from {0} to {1} by {2} ({3}) at {4} *{0} is original sampleID, {1} is new sampleID, {2} is Firstname Lastname of the operator who made the change, {3} is operatorID of the operator who made the change, and {4} is DateTime of the change.	Present when an operator changes a sample ID after the test finished, and manually resent the run up to the connected information system.			
QC Designated Test				
Comment	Reporting Condition			
Action: Consult the Interpretation of Results table in Quick Guide.	Present when a run has a QC Result of Fail.			
Action: Retest once. If problem persists, contact bioMérieux Customer Support.	Present when the internal pouch controls fail.			
PCR Test	Always present.			

4. BIOFIRE[®] SPOTFIRE[®] Respiratory/Sore Throat Panel Pouch

The BIOFIRE[®] SPOTFIRE[®] Respiratory/Sore Throat Panel (referred to as the SPOTFIRE R/ST Panel), run using a SPOTFIRE R/ST Panel pouch, is used to detect and discriminate upper respiratory pathogens in samples from individuals with signs or symptoms of upper respiratory tract infections. The SPOTFIRE R/ST Panel encompasses two test menus, each with a unique set of pathogens: Respiratory and Sore Throat.

An electronic report for the SPOTFIRE R/ST Panel contains information from a single test menu run using an R/ST Panel pouch.

4.1. SPOTFIRE Respiratory/Sore Throat Panel Disposable (Pouch)

The SPOTFIRE R/ST Panel is run using a pouch as the disposable, whose properties are indicated in Table 4.1.1.

Table 4.1.1: Disposable (Pouch)

Name	Coding System
R/ST Panel	BMX

4.2. SPOTFIRE Respiratory/Sore Throat Panel Universal Order/Service ID (Panel)

The SPOTFIRE R/ST Panel pouch is used to test for one of two applicable menus: Respiratory or Sore Throat. Each menu is a syndromic test comprised of multiple pathogens.

The panel menu (or test) properties for each panel are indicated in Table 4.2.1.

Table 4.2.1: Universal Order/Service ID (Panel Menu)

Code	Display Name	Coding System
RM	Respiratory Menu	BMX
STM	Sore Throat Menu	BMX

WARNING: The Universal Order/Service ID Code for the Respiratory Menu will change pending FDA feedback.

4.3. SPOTFIRE Respiratory/Sore Throat Panel Associated Sample Type(s)

The SPOTFIRE R/ST Panel pouch may be used with a subset of cleared sample type(s), whose properties are indicated in Table 4.3.1.

Note that each sample type may only be cleared for use for some of the test menus available on the pouch. This is indicated in the Associated Panel column.

Table 4.3.1: Associated	Sample Type(s)
-------------------------	----------------

Code	Display Name	Coding System	Associated Panel(s) (from Table 4.2.1)
NPS	Nasopharyngeal Swab	BMX	Respiratory Menu
THR	Throat Swab	BMX	Sore Throat Menu

4.4. SPOTFIRE Respiratory/Sore Throat Panel Possible Panel Results

The possible results (derived from Table 1.3.1) for the SPOTFIRE R/ST Panel are indicated in Table 4.4.1. Note that not every result in Table 4.4.1 will be associated with all of the SPOTFIRE R/ST Panel menu observations. Refer to sections 4.5 and 4.6 to see which of the possible results each observation on the panel menu may be associated with.

Qualitative Results Coding System: BMX		
Code	Display Name	Result Number
POS	Positive	1
NEG	Negative	2
UNCERT	Uncertain	3
PASS	Pass	100
FAIL	Fail	101
INVALID	Invalid	102
INV_CF	Invalid Internal Process Control Failure	200
INV_AB	Invalid Aborted Run	201
INV_SE	Invalid Software Error	202
INV_IE	Invalid Instrument Error	203
INV_RI	Invalid Run Incomplete	204
INV_OC	Invalid Operational Conditions Out of Range	205
Quantitative Results Coding system: UCUM		
71.52 Cel^DegreeCelsius Note: 71.52 is displayed for exa	mple purposes only. This value will be populated with data from the system.	300

Table 4.4.1: Possible Panel Results

4.5. SPOTFIRE Respiratory/Sore Throat Panel Possible Panel Observations

The SPOTFIRE R/ST Panel tests for a set of observations based on a specific syndrome. The observations on the SPOTFIRE R/ST Panel menus and their properties are indicated in:

- Table 4.5.1.1: Patient Designated Tests (for Respiratory Menu)
- Table 4.5.1.2: Patient Designated Tests (for Sore Throat Menu)
- Table 4.5.2: QC Designated Tests

Table 4.5.1.1: Panel Observations for Patient Designated Tests (for Respiratory Menu)

Run Status Observations Coding system: BMX

Code	Display Name	Possible Result Number(s) (from Table 4.4.1)	Possible Result Code(s) (from Table 4.4.1)
		100	PASS
		200	INV_CF
		201	INV_AB
RUN_STAT	Run Status	202	INV_SE
		203	INV_IE
		204	INV_RI
		205	INV_OC
Target Observations Coding System: BMX			
Code	Display Name	Possible Result Number(s) (from Table 4.4.1)	Possible Result Code(s) (from Table 4.4.1)
PSTv01001	Adapavirua	1	POS
K31X01001	Adenovirus	2	NEG
BSTy02001	Pordotalla parapartuasia	1	POS
K31X02001	Dordetella parapertussis	2	NEG
BSTv02002	Pordotalla portugaia	1	POS
R31X02002	Bordetella parapertussis 1 100 Bordetella parapertussis 2 NEG Bordetella pertussis 1 POS 2 NEG	NEG	
DSTv02002	Chlemydia proumoniae	1	POS
R31X02003	Chiamydia pheumoniae	2	NEG
PSTv01002		1	POS
K31X01002	Coronavirus SARS-Cov-2	2	NEG
DCT_01002		1	POS
K31X01003	Coronavirus (seasonar)	2	NEG
PSTv01004		1	POS
K31X01004	Human metapheumovirus	2	NEG
DOTV04005		1	POS
KS1X01005	Human minovirus/enterovirus	2	NEG
		1	POS
RSTx01006	Influenza A virus	2	NEG
		3	UNCERT
DSTv01007		1	POS
		2	NEG
DSTv01009		1	POS
N31XU1000		2	NEG

RST_01000	Influenza B virus	1	POS
1/31/01/009		2	NEG
PSTx02004	Myconlagma proumoniao	1	POS
K31x02004		2	NEG
PSTv01010	Parainfluonza virus	1	POS
131201010	Falaininuenza virus	2	NEG
RSTx01011	Respiratory syncytial virus	1	POS
		2	NEG
Control Observations Coding System: BMX			
Code	Display Name	Possible Result Number(s) (from Table 4.4.1)	Possible Result Code(s) (from Table 4.4.1)
	PCR2 Control	100	PASS
FORZ_OTTL	PCR2 Control	FAIL	
	DCD2 Control Try Volue A	200	Quantitative (variable)
PCR2C_TM_A		300	reporting of this observation
			Quantitative (variable)
PCR2C_TM_B	PCR2 Control Tm Value B	300	*see section 2.6 for conditional reporting of this observation
DOD20 TM C	PCP2 Control Try Volue C	200	Quantitative (variable)
PCR2C_TM_C		300	reporting of this observation
	PNA Process Control	100	PASS
KINA_UTKL	KINA Process Control	101	FAIL
			Quantitative (variable)
KNAC_IM_A	KINA Process Control 1m Value A	300	*see section 2.6 for conditional reporting of this observation
		300	Quantitative (variable)
RNAC_TM_B	RNA Process Control Tm Value B		*see section 2.6 for conditional reporting of this observation
PNAC TM C	PNA Process Control Try Volue C	200	Quantitative (variable)
	TANA FIOLESS CONTOL THE VALUE C	300	reporting of this observation

Run Status Observat	tions		
Code	Display Name	Possible Result Number(s) (from Table 4.4.1)	Possible Result Code(s) (from Table 4.4.1)
		100	PASS
		200	INV_CF
		201	INV_AB
RUN_STAT	Run Status	202	INV_SE
		203	INV_IE
		204	INV_RI
		205	INV_OC
Target Observations Coding System: BMX			
Code	Display Name	Possible Result Number(s) (from Table 4.4.1)	Possible Result Code(s) (from Table 4.4.1)
		1	POS
RSTx01001	Adenovirus	2	NEG
		1	POS
RSTx02003	Chlamydia pneumoniae	2	NEG
		1	POS
RSTx01002	Coronavirus SARS-CoV-2	2	NEG
		1	POS
RSTx01003	Coronavirus (seasonal)	2	NEG
		1	POS
RSTx01004	Human metapneumovirus	2	NEG
		1	POS
RSTx01005	Human rhinovirus/enterovirus	2	NEG
		1	POS
RSTx01006	Influenza A virus	2	NEG
		3	UNCERT
		1	POS
RSTx01007	Influenza A virus A/H1-2009	2	NEG
			POS
RSTx01008	Influenza A virus A/H3	2	NEG
RSTx01009	Influenza B virus	1	POS

Table 4.5.1.2: Panel Observations for Patient Designated Tests (for Sore Throat Menu)

		2	NEG
DCT:/02004		1	POS
RS1X02004	Mycopiasma prieumoniae	2	NEG
DST:/01010	Dereinfluenze virue	1	POS
KSTXUIUIU	Parainnuenza virus		NEG
BST/01011	De avierte en estiste de la com	1	POS
KSTX01011	Respiratory syncytial virus	2	NEG
DST:00005	Streptococcus dvsgalactiae (group C/G	1	POS
K51X02005	Strep)	2	NEG
DST/02006	Streptococcus pyogenes (group A	1	POS
R51X02006	Strep)	2	NEG
Control Observations Coding System: BMX			
Code	Display Name	Possible Result Number(s) (from Table 4.4.1)	Possible Result Code(s) (from Table 4.4.1)
	PCR2 Control	100	PASS
FORZ_GIRE		101	FAIL
PCR2C_TM_A	C TM A PCR2 Control Tm Value A		Quantitative (variable) *see section 2.6 for conditional
			reporting of this observation
PCR2C_TM_B	PCR2 Control Tm Value B	300	Quantitative (variable) *see section 2.6 for conditional reporting of this observation
PCR2C_TM_C	PCR2 Control Tm Value C	300	Quantitative (variable) *see section 2.6 for conditional reporting of this observation
	RNA Process Control	100	PASS
		101	FAIL
RNAC_TM_A	RNA Process Control Tm Value A	300	Quantitative (variable) *see section 2.6 for conditional reporting of this observation
RNAC_TM_B	RNA Process Control Tm Value B	300	Quantitative (variable) *see section 2.6 for conditional reporting of this observation
			Quantitative (variable)

	coding system: BMX			
	Code	Display Name	Possible Result Number(s) (from Table 4.4.1)	Possible Result Code(s) (from Table 4.4.1)
			100	PASS
	RUN_STAT		200	INV_CF
			201	INV_AB
		Run Status	202	INV_SE
			203	INV_IE
			204	INV_RI
			205	INV_OC
	QC Result Observations Coding system: BMX			
	Code	Display Name	Possible Result Number(s) (from Table 4.4.1)	Possible Result Code(s) (from Table 4.4.1)
			100	PASS
	QC_RSLT	QC Result	101	FAIL
			102	INVALID
Target Observations Coding System: BMX				
	Code	Display Name	Possible Result Number(s) (from Table 4.4.1)	Possible Result Code(s) (from Table 4.4.1)
	RPx01001	Adopovinuo	1	POS
		Adenovirus	2	NEG
	RPx02001	Pardetalla parapartuasia	1	POS
			2	NEG
	20,0000	Doudotello nortugoio	1	POS
	RFX02002	bordetella pertussis	2	NEG
	DDv02002	Chlamydia pneumoniae	1	POS
	RPx02003		2	NEG
	RPx01002		1	POS
			2	NEG
	PPv01003		1	POS
	RFXU1003	Coronavirus (seasofiar)	2	NEG
	RPx01004	Human metapneumovirus	1	POS

Table 2.5.2: Panel Observations for QC Designated Tests

		2	NEG
DD::04005		1	POS
RPx01005 Human rhinovirus/enterovirus		2	NEG
DD::01000		1	POS
RPX01006	Influenza A virus	2	NEG
	1. fluence A	1	POS
RPX01007	Influenza A virus A/H1-2009	2	NEG
DD::01000		1	POS
RPX01008	Influenza A virus A/H3	2	NEG
DD::01000	Influence During	1	POS
RPX01009	Influenza B virus	2	NEG
DD://000/		1	POS
	wycopiasma pneumoniae	2	NEG
		1	POS
RPX01010	Paraimuenza virus	2	NEG
PDv01011	Peopiratory expecticly virue	1	POS
RPXUIUTI	Respiratory syncytial virus	2	NEG
DST_02005	Streptococcus dysgalactiae (group C/G Strep)	1	POS
RSTx02005		2	NEG
Streptococ			
DOT: 00000	Streptococcus pyogenes (group A	1	POS
RSTx02006	Streptococcus pyogenes (group A Strep)	1 2	POS NEG
RSTx02006 Control Observations Coding System: BMX	Streptococcus pyogenes (group A Strep)	2	NEG
RSTx02006 Control Observations Coding System: BMX Code	Streptococcus pyogenes (group A Strep)	1 2 Possible Result Number(s) (from Table 4.4.1)	POS NEG Possible Result Code(s) (from Table 4.4.1)
RSTx02006 Control Observations Coding System: BMX Code	Streptococcus pyogenes (group A Strep) Display Name	1 2 Possible Result Number(s) (from Table 4.4.1) 100	POS NEG Possible Result Code(s) (from Table 4.4.1) PASS
RSTx02006 Control Observations Coding System: BMX Code PCR2_CTRL	Streptococcus pyogenes (group A Strep) Display Name PCR2 Control	1 2 Possible Result Number(s) (from Table 4.4.1) 100 101	POS NEG Possible Result Code(s) (from Table 4.4.1) PASS FAIL
RSTx02006 Control Observations Coding System: BMX Code PCR2_CTRL PCR2C_TM_A	Streptococcus pyogenes (group A Strep) Display Name PCR2 Control PCR2 Control Tm Value A	1 2 Possible Result Number(s) (from Table 4.4.1) 100 101 300	POS NEG Possible Result Code(s) (from Table 4.4.1) PASS FAIL Quantitative (variable) *see section 2.6 for conditional reporting of this observation
RSTx02006 Control Observations Coding System: BMX Code PCR2_CTRL PCR2C_TM_A PCR2C_TM_B	Streptococcus pyogenes (group A Strep) Display Name PCR2 Control PCR2 Control Tm Value A PCR2 Control Tm Value B	1 2 Possible Result Number(s) (from Table 4.4.1) 100 101 300 300	POS NEG Possible Result Code(s) (from Table 4.4.1) PASS FAIL Quantitative (variable) *see section 2.6 for conditional reporting of this observation Quantitative (variable) *see section 2.6 for conditional reporting of this observation
RSTx02006 Control Observations Coding System: BMX Code PCR2_CTRL PCR2C_TM_A PCR2C_TM_B PCR2C_TM_C	Streptococcus pyogenes (group A Strep) Display Name PCR2 Control PCR2 Control Tm Value A PCR2 Control Tm Value B PCR2 Control Tm Value C	1 2 Possible Result Number(s) (from Table 4.4.1) 100 101 300 300 300	POS NEG Possible Result Code(s) (from Table 4.4.1) PASS FAIL Quantitative (variable) *see section 2.6 for conditional reporting of this observation Quantitative (variable) *see section 2.6 for conditional reporting of this observation Quantitative (variable) *see section 2.6 for conditional reporting of this observation Quantitative (variable) *see section 2.6 for conditional reporting of this observation Quantitative (variable) *see section 2.6 for conditional reporting of this observation
RSTx02006 Control Observations Coding System: BMX Code PCR2_CTRL PCR2C_TM_A PCR2C_TM_B PCR2C_TM_C	Streptococcus pyogenes (group A Strep) Display Name PCR2 Control PCR2 Control Tm Value A PCR2 Control Tm Value B PCR2 Control Tm Value C	1 2 Possible Result Number(s) (from Table 4.4.1) 100 101 300 300 300 100	POS NEG Possible Result Code(s) (from Table 4.4.1) PASS FAIL Quantitative (variable) *see section 2.6 for conditional reporting of this observation Quantitative (variable) *see section 2.6 for conditional reporting of this observation Quantitative (variable) *see section 2.6 for conditional reporting of this observation PASS

RNAC_TM_A	RNA Process Control Tm Value A	300	Quantitative (variable) *see section 2.6 for conditional reporting of this observation
RNAC_TM_B	AC_TM_B RNA Process Control Tm Value B		Quantitative (variable) *see section 2.6 for conditional reporting of this observation
RNAC_TM_C	RNA Process Control Tm Value C	300	Quantitative (variable) *see section 2.6 for conditional reporting of this observation

4.6. SPOTFIRE Respiratory/Sore Throat Panel Observation Conditional Reporting

Some observations on the SPOTFIRE R/ST Panel menus are conditionally reported on the electronic report, as indicated in section 4.5. The reporting conditions for conditionally reported observations on the SPOTFIRE R/ST Panel menus are indicated in Table 4.6.1.

Table 4.6.1: Conditional Reporting

Observation Display Name (from Table 4.5.1.1, 4.5.1.2 and/or 4.5.2)	Result Display Name (from Table 4.4.1)	Reporting Condition
PCR2 Control Tm Value A PCR2 Control Tm Value B PCR2 Control Tm Value C	Quantitative (variable)	An observation is included in the electronic report for each Control pouch well for which a Tm value was found. Note that A, B, and C correlate directly to a specific well on the pouch array. e.g., if two Tm values are found for the PCR2 control, only two of the three observations will be sent
		Otherwise, the observation is not included in the electronic report.
RNA Process Control Tm Value A RNA Process Control Tm Value B RNA Process Control Tm Value C	Quantitative (variable)	An observation is included in the electronic report for each Control pouch well for which a Tm value was found. Note that A, B, and C correlate directly to a specific well on the pouch array. e.g., if two Tm values are found for the PCR2 control, only two of the three observations will be sent
		Otherwise, the observation is not included in the electronic report.

4.7. SPOTFIRE Respiratory/Sore Throat Panel Warnings and Notes

The SPOTFIRE R/ST Panel is associated with warnings or notes that give additional information to help with interpretation of the information on the report, as indicated in Table 4.7.1.

Table 4.7.1: Test Notes

Patient Designated Test			
Comment	Reporting Condition		
Action: This result is uncommon. Consult the Interpretation of Results table in Quick Guide.	 Present when any of the following apply for a run: 4+ organisms have positive results an organism(s) has an uncertain result Influenza A virus has a positive result, Influenza A virus A/H1-2009 and Influenza A virus A/H3 both have negative results all Influenza A and B strains have positive results 		
Action: Retest once. If problem persists, contact bioMérieux Customer Support.	Present when the internal pouch controls fail.		
PCR Test	Always present.		
Edit History: Sample ID changed from {0} to {1} by {2} ({3}) at {4} *{0} is original sampleID, {1} is new sampleID, {2} is Firstname Lastname of the operator who made the change, {3} is operatorID of the operator who made the change, and {4} is DateTime of the change.	Present when an operator changes a sample ID after the test finished, and manually resent the run up to the connected information system.		
QC Designated Test			
Comment	Reporting Condition		
Action: Consult the Interpretation of Results table in Quick Guide.	Present when a run has a QC Result of Fail.		
Action: Retest once. If problem persists, contact bioMérieux Customer Support.	Present when the internal pouch controls fail.		
PCR Test	Always present.		

5. Technical Support Contact Information

bioMérieux is dedicated to providing the best customer support available. If you have any questions or concerns about this process, please contact Technical Support for assistance.

Technical Support

Email: <u>biofiresupport@biomerieux.com</u> Phone: +1-801-736-6354, select Option 5





© 2023 bioMérieux, Inc. All rights reserved. Under the copyright laws, this document may not be copied, in whole or in part, without the written consent of bioMérieux.

bioMérieux, Inc. 515 Colorow Drive Salt Lake City, Utah 84108 USA 1-801-736-6354 1 800 735 6544 www.biomerieux.com

BIOMÉRIEUX, the BIOMÉRIEUX logo, PIONEERING DIAGNOSTICS, BIOFIRE, and SPOTFIRE are used, pending and/or registered trademarks belonging to bioMérieux, or one of its subsidiaries, or one of its companies. Any other company and product names mentioned herein may be trademarks of their respective companies. Mention of third-party products is for informational purposes only and does not constitute an endorsement. bioMérieux assumes no responsibility with regard to the performance or use of these third-party products.

BFR0001-9777-04