

BIOFIRE® SPOTFIRE® CONNECTIVITY SOFTWARE MAPPING GUIDE

BIOFIRE® SPOTFIRE® System

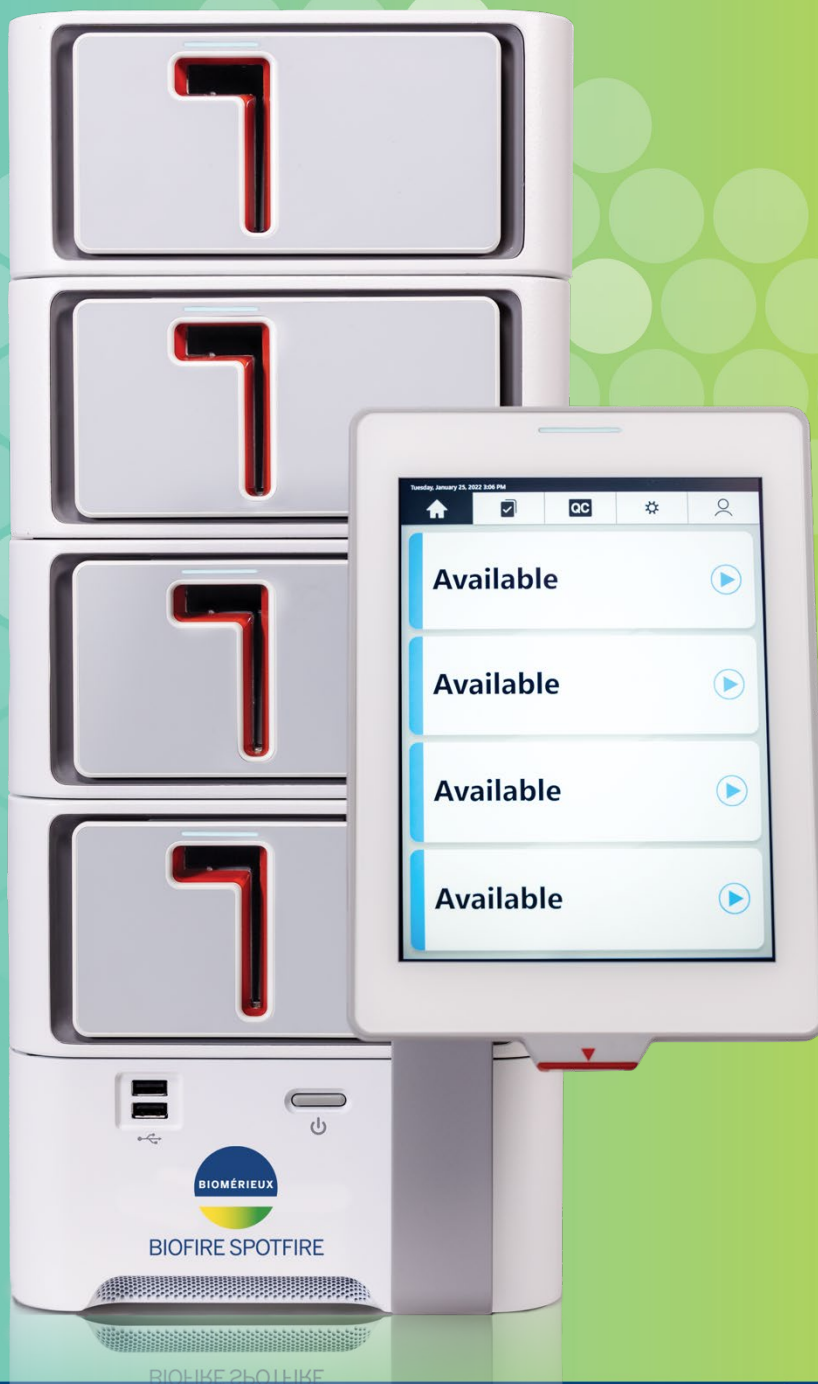


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Document Revision History

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 Added warning that the Respiratory Menu (on R/ST) Universal Order/Service ID will change pending FDA feedback	10/2023
BFR0001-9777-05	Added two Respiratory/Sore Throat sections due to multiple software versions (v4.0.4 and v4.0.100): <ul style="list-style-type: none"> • v4.0.4: Coronavirus SARS-CoV-2 Reported <ul style="list-style-type: none"> ○ Updated the Respiratory Menu Universal Order/Service ID ○ Added new fields and information for HL7/XML ○ Corrected misrepresented codes ○ Updated list of warnings/notes • v4.0.100: Coronavirus SARS-CoV-2 Not Reported <ul style="list-style-type: none"> ○ New section added Added information related to new message types: HL7 and XML Added warning related to the DateTime format of the SampleID change annotation for all panels	04/2024
BFR0001-9777-06	Added Respiratory/Sore Throat Mini Panel section Updated Respiratory Panel and Respiratory Panel Mini sections <ul style="list-style-type: none"> • Added information related to new message types: HL7 and XML • Updated annotations 	08/2024
BFR0001-9777-07	Updated Respiratory/Sore Throat Mini Panel section for change of sample type from Nasopharyngeal Swab to Nasal Swab/Nasopharyngeal Swab Updated color code in Section 1.4 from Panel to Panel Family	03/2025
BFR0001-9777-08	Added Respiratory/Sore Throat <i>plus</i> and Respiratory/Sore Throat <i>plus</i> Mini sections Updated typo in sections X.6.1 to refer to RNA process control instead of PCR2 control	02/2026

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 component of 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, laboratory information system) to electronically transfer test information. There are three supported implementations:

1. **POCT:**
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.
2. **XML:**
A unidirectional XML flat-file transfer or transfer of structured text from the SPOTFIRE System to a data manager, referred to as the XML interface throughout this document.
WARNING: QC is not currently supported for HL7 or XML.
3. **HL7:**
A unidirectional or bidirectional transfer of structured data sets from the SPOTFIRE System to a data manager utilizing HL7 v2.5.1 based on the CLSI AUTO16 standard, referred to as the HL7 interface throughout this document.
WARNING: QC is not currently supported for HL7 or XML.

Note that some of the information in this document may not apply to all interface types, which will be indicated in the corresponding section.

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 observations 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, or by all observations on the 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.

Table 1.3.1: All Possible Observation Results

Qualitative Results		
<i>Coding System: BMX (for POCT or XML), 99BMX (for HL7)</i>		
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
IN_PROG	In Progress	400
Quantitative Results		
Representation	Supported Interface Type	Result Number
<i>Note: 71.52 below is displayed for example purposes only. This value will be populated with data from the system.</i>		
<OBS.value> : <ul style="list-style-type: none"> V="71.52" U="Cel^DegreeCelsius^UCUM" 	POCT	300
OBX-5: 71.52 OBX-6: Cel^DegreesCelsius^UCUM	HL7	
<valueType> : NM <observationValue> : 71.52 <observationName> : DegreesCelsius	XML	

- Subsection 5 provides all of the possible observations for the SPOTFIRE Panel(s), for both Patient and QC designated runs, which result groups the observations are grouped under, 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.

For reference, all possible result groups are provided in Table 1.3.2. Note that not every possible result group may be used by a SPOTFIRE Pouch. Users should refer to subsections 5 and 6 for the respective SPOTFIRE Pouch to see which possible result groups the observations on a SPOTFIRE Pouch may be associated with.

Table 1.3.2: All Possible Result Groups

WARNING: Result groups are only reported for XML and HL7 Group Annotations.

Qualitative Results		
Coding System: BMX (for POCT or XML), 99BMX (for HL7)		
Code	Display Name	Observation Code Assignment
PNLRSLT	Panel Results	
VIRUSE	Viruses	01
BACTER	Bacteria	02
CNTRLS	Control Results	
QCRSLT	QC Result	

Note: Each observation code utilizes the Observation Code Assignment value within the code to indicate which result group it is associated with (e.g., RSTx01001 means the observation associated with this code is part of the Viruses result group).

- Subsection 6 provides any conditional reporting rules that may apply to the observations on the SPOTFIRE 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 Family to improve readability, as follows:

Color	Panel Family
	Respiratory/Sore Throat

2. BIOFIRE® SPOTFIRE® Respiratory/Sore Throat Panel Pouch

v4.0.4: Software Reports Coronavirus SARS-CoV-2 for the Throat Swab Sample Type

WARNING: Because throat swab as a sample type for Coronavirus SARS-CoV-2 detection may vary by location, there are two versions of the BIOFIRE® SPOTFIRE® Respiratory/Sore Throat Panel software associated with the pouch:

- **v4.0.4:** Reports Coronavirus SARS-CoV-2 for the Throat Swab sample type
- **v4.0.100:** Does not report Coronavirus SARS-CoV-2 for the Throat Swab sample type (see Section 3)

Users of this guide should verify the appropriate version used by institution for proper mapping. Contact your local bioMérieux subsidiary or distributor for details.

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.

2.1. 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 2.1.1.

Table 2.1.1: Disposable (Pouch)

Name	Coding System
R/ST Panel	BMX

Note: If utilizing HL7, the Coding System will be prepended with "99" (i.e., 99BMX).

2.2. 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 2.2.1.

WARNING: QC is not currently supported for HL7 or XML.

Table 2.2.1: Universal Order/Service ID (Panel Menu)

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

Note: If utilizing HL7, the Coding System will be prepended with "99" (i.e., 99BMX).

2.3. 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 2.3.1.

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 2.3.1: Associated Sample Type(s)

Code	Display Name	Coding System	Associated Panel Menu(s) <i>(from Table 2.2.1)</i>
NPS	Nasopharyngeal Swab	BMX	Respiratory Menu
THR	Throat Swab	BMX	Sore Throat Menu

Note: If utilizing HL7, the Coding System will be prepended with "99" (i.e., 99BMX).

2.4. SPOTFIRE Respiratory/Sore Throat Panel Possible Panel Results and Result Groupings

The possible results (derived from Table 1.3.1) for the SPOTFIRE R/ST 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/ST Panel menu observations. Refer to sections 2.5 and 2.6 to see which of the possible results each observation on the panel menu may be associated with.

Table 2.4.1: Possible Panel Results

Qualitative Results		
<i>Coding System: BMX (for POCT or XML), 99BMX (for HL7)</i>		
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
IN_PROG	In Progress	400
Quantitative Results		
<i>See representation of quantitative results, based on the supported interface type, in Table 1.3.1.</i>		300

The possible result groups (derived from Table 1.3.2) for the SPOTFIRE R/ST Panel are indicated in Table 2.4.2. Refer to sections 2.5 and 2.6 to see which of the result groups each observation on the panel is associated with.

Table 2.4.2: Possible Panel Result Groups

WARNING: Result groups are only reported for XML and HL7 Group Annotations.

Qualitative Results		
<i>Coding System: BMX (for POCT or XML), 99BMX (for HL7)</i>		
Code	Display Name	Observation Code Assignment
PNLRSLT	Panel Results	
VIRUSE	Viruses	01
BACTER	Bacteria	02
CNTRLS	Control Results	
QCRSLT	QC Result	

2.5. 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 2.5.1.1: Patient Designated Tests (for Respiratory Menu)
- Table 2.5.1.2: Patient Designated Tests (for Sore Throat Menu)
- Table 2.5.2: QC Designated Tests

WARNING: QC is not currently supported for HL7 or XML.

Table 2.5.1.1: Panel Observations for Patient Designated Tests (for Respiratory Menu)

Run Status Observations					
Coding system: BMX (for POCT or XML), 99BMX (for HL7)					
Result Group Code <small>(from Table 2.4.2)</small>	Result Group Display Name <small>(from Table 2.4.2)</small>	Observation Code	Observation Display Name	Possible Result Number(s) <small>(from Table 2.4.1)</small>	Possible Result Code(s) <small>(from Table 2.4.1)</small>
PNLRSLT	Panel Results	RUN_STAT	Run Status	100	PASS
				200	INV_CF
				201	INV_AB
				202	INV_SE
				203	INV_IE
				204	INV_RI
				205	INV_OC
				400	IN_PROG
Target Observations					
Coding System: BMX (for POCT or XML), 99BMX (for HL7)					
Result Group Code <small>(from Table 2.4.2)</small>	Result Group Display Name <small>(from Table 2.4.2)</small>	Observation Code	Observation Display Name	Possible Result Number(s) <small>(from Table 2.4.1)</small>	Possible Result Code(s) <small>(from Table 2.4.1)</small>
VIRUSE	Viruses	RSTx01001	Adenovirus	1	POS
				2	NEG
		RSTx01002	Coronavirus SARS-CoV-2	1	POS
				2	NEG
		RSTx01003	Coronavirus (seasonal)	1	POS
				2	NEG
		RSTx01004	Human metapneumovirus	1	POS
				2	NEG
		RSTx01005	Human rhinovirus/enterovirus	1	POS

		RSTx01006	Influenza A virus	2	NEG
				1	POS
				2	NEG
				3	UNCERT
		RSTx01007	Influenza A virus A/H1-2009	1	POS
				2	NEG
		RSTx01008	Influenza A virus A/H3	1	POS
				2	NEG
		RSTx01009	Influenza B virus	1	POS
				2	NEG
		RSTx01010	Parainfluenza virus	1	POS
				2	NEG
		RSTx01011	Respiratory syncytial virus	1	POS
				2	NEG
BACTER	Bacteria	RSTx02001	Bordetella parapertussis	1	POS
				2	NEG
		RSTx02002	Bordetella pertussis	1	POS
				2	NEG
		RSTx02003	Chlamydia pneumoniae	1	POS
				2	NEG
		RSTx02004	Mycoplasma pneumoniae	1	POS
				2	NEG
Control Observations					
Coding System: BMX (for POCT or XML), 99BMX (for HL7)					
Result Group Code <i>(from Table 2.4.2)</i>	Result Group Display Name <i>(from Table 2.4.2)</i>	Observation Code	Observation Display Name	Possible Result Number(s) <i>(from Table 2.4.1)</i>	Possible Result Code(s) <i>(from Table 2.4.1)</i>
CNTRLS	Control Results	PCR2_CTRL	PCR2 Control	100	PASS
				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_CTRL	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
		RNAC_TM_C	RNA Process Control Tm Value C	300	Quantitative (variable) *see section 2.6 for conditional reporting of this observation

Note: Possible result values shown in blue will only be sent when the SPOTFIRE System is set to transmit failed run data. Possible result values shown in yellow will only be sent when the SPOTFIRE System is set to transmit start test notifications. Observation values shown in red will only be sent when the SPOTFIRE System is set to transmit control values; however, Control Tm values are only sent for passing runs. These features may be toggled on/off in the SPOTFIRE settings menu.

Table 2.5.1.2: Panel Observations for Patient Designated Tests (for Sore Throat Menu)

Run Status Observations					
Coding system: BMX (for POCT or XML), 99BMX (for HL7)					
Result Group Code <i>(from Table 2.4.2)</i>	Result Group Display Name <i>(from Table 2.4.2)</i>	Observation Code	Observation Display Name	Possible Result Number(s) <i>(from Table 2.4.1)</i>	Possible Result Code(s) <i>(from Table 2.4.1)</i>
PNLRSLT	Panel Results	RUN_STAT	Run Status	100	PASS
				200	INV_CF
				201	INV_AB
				202	INV_SE
				203	INV_IE
				204	INV_RI
				205	INV_OC
				400	IN_PROG
Target Observations					
Coding System: BMX (for POCT or XML), 99BMX (for HL7)					
Result Group Code <i>(from Table 2.4.2)</i>	Result Group Display Name <i>(from Table 2.4.2)</i>	Observation Code	Observation Display Name	Possible Result Number(s) <i>(from Table 2.4.1)</i>	Possible Result Code(s) <i>(from Table 2.4.1)</i>
VIRUSE	Viruses	RSTx01001	Adenovirus	1	POS
				2	NEG
		RSTx01002	Coronavirus SARS-CoV-2	1	POS
				2	NEG
		RSTx01003	Coronavirus (seasonal)	1	POS
				2	NEG
		RSTx01004	Human metapneumovirus	1	POS
				2	NEG
		RSTx01005	Human rhinovirus/enterovirus	1	POS
				2	NEG
		RSTx01006	Influenza A virus	1	POS
				2	NEG
				3	UNCERT
		RSTx01007	Influenza A virus A/H1-2009	1	POS
				2	NEG
		RSTx01008	Influenza A virus A/H3	1	POS
2	NEG				

		RSTx01009	Influenza B virus	1	POS
				2	NEG
		RSTx01010	Parainfluenza virus	1	POS
				2	NEG
		RSTx01011	Respiratory syncytial virus	1	POS
				2	NEG
BACTER	Bacteria	RSTx02003	Chlamydia pneumoniae	1	POS
				2	NEG
		RSTx02004	Mycoplasma pneumoniae	1	POS
				2	NEG
		RSTx02005	Streptococcus dysgalactiae (group C/G Strep)	1	POS
				2	NEG
		RSTx02006	Streptococcus pyogenes (group A Strep)	1	POS
				2	NEG
Control Observations					
Coding System: BMX (for POCT or XML), 99BMX (for HL7)					
Result Group Code <i>(from Table 2.4.2)</i>	Result Group Display Name <i>(from Table 2.4.2)</i>	Observation Code	Observation Display Name	Possible Result Number(s) <i>(from Table 2.4.1)</i>	Possible Result Code(s) <i>(from Table 2.4.1)</i>
CNTRLS	Control Results	PCR2_CTRL	PCR2 Control	100	PASS
				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_CTRL	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		

			RNAC_TM_C	RNA Process Control Tm Value C	300	Quantitative (variable) *see section 2.6 for conditional reporting of this observation
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Note: Possible result values shown in blue will only be sent when the SPOTFIRE System is set to transmit failed run data. Possible result values shown in yellow will only be sent when the SPOTFIRE System is set to transmit start test notifications. Observation values shown in red will only be sent when the SPOTFIRE System is set to transmit control values; however, Control Tm values are only sent for passing runs. These features may be toggled on/off in the SPOTFIRE settings menu.

Table 2.5.2: Panel Observations for QC Designated Tests

Run Status Observations					
<i>Coding system: BMX (for POCT or XML), 99BMX (for HL7)</i>					
Result Group Code <small>(from Table 2.4.2)</small>	Result Group Display Name <small>(from Table 2.4.2)</small>	Observation Code	Observation Display Name	Possible Result Number(s) <small>(from Table 2.4.1)</small>	Possible Result Code(s) <small>(from Table 2.4.1)</small>
PNLRSLT	Panel Results	RUN_STAT	Run Status	100	PASS
				200	INV_CF
				201	INV_AB
				202	INV_SE
				203	INV_IE
				204	INV_RI
				205	INV_OC
				400	IN_PROG
QC Result Observations					
<i>Coding system: BMX (for POCT or XML), 99BMX (for HL7)</i>					
Result Group Code <small>(from Table 2.4.2)</small>	Result Group Display Name <small>(from Table 2.4.2)</small>	Observation Code	Observation Display Name	Possible Result Number(s) <small>(from Table 2.4.1)</small>	Possible Result Code(s) <small>(from Table 2.4.1)</small>
QCRSLT	QC Result	QC_RSLT	QC Result	100	PASS
				101	FAIL
				102	INVALID
Target Observations					
<i>Coding System: BMX (for POCT or XML), 99BMX (for HL7)</i>					
Result Group Code <small>(from Table 2.4.2)</small>	Result Group Display Name <small>(from Table 2.4.2)</small>	Observation Code	Observation Display Name	Possible Result Number(s) <small>(from Table 2.4.1)</small>	Possible Result Code(s) <small>(from Table 2.4.1)</small>
VIRUSE	Viruses	RSTx01001	Adenovirus	1	POS
				2	NEG
		RSTx01002	Coronavirus SARS-CoV-2	1	POS
				2	NEG
		RSTx01003	Coronavirus (seasonal)	1	POS
				2	NEG
		RSTx01004	Human metapneumovirus	1	POS
				2	NEG

		RSTx01005	Human rhinovirus/enterovirus	1	POS
				2	NEG
		RSTx01006	Influenza A virus	1	POS
				2	NEG
		RSTx01007	Influenza A virus A/H1-2009	1	POS
				2	NEG
		RSTx01008	Influenza A virus A/H3	1	POS
				2	NEG
		RSTx01009	Influenza B virus	1	POS
				2	NEG
		RSTx01010	Parainfluenza virus	1	POS
				2	NEG
		RSTx01011	Respiratory syncytial virus	1	POS
				2	NEG
BACTER	Bacteria	RSTx02001	Bordetella parapertussis	1	POS
				2	NEG
		RSTx02002	Bordetella pertussis	1	POS
				2	NEG
		RSTx02003	Chlamydia pneumoniae	1	POS
				2	NEG
		RSTx02004	Mycoplasma pneumoniae	1	POS
				2	NEG
		RSTx02005	Streptococcus dysgalactiae (group C/G Strep)	1	POS
				2	NEG
		RSTx02006	Streptococcus pyogenes (group A Strep)	1	POS
				2	NEG
Control Observations					
Coding System: <i>BMX</i> (for POCT or XML), <i>99BMX</i> (for HL7)					
Result Group Code <small>(from Table 2.4.2)</small>	Result Group Display Name <small>(from Table 2.4.2)</small>	Observation Code	Observation Display Name	Possible Result Number(s) <small>(from Table 2.4.1)</small>	Possible Result Code(s) <small>(from Table 2.4.1)</small>
CNTRL	Control Results	PCR2_CTRL	PCR2 Control	100	PASS
				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_CTRL	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
		RNAC_TM_C	RNA Process Control Tm Value C	300	Quantitative (variable) *see section 2.6 for conditional reporting of this observation

Note: Possible result values shown in blue will only be sent when the SPOTFIRE System is set to transmit failed run data. Possible result values shown in yellow will only be sent when the SPOTFIRE System is set to transmit start test notifications. Observation values shown in red will only be sent when the SPOTFIRE System is set to transmit control values; however, Control Tm values are only sent for passing runs. These features may be toggled on/off in the SPOTFIRE settings menu.

2.6. 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 2.5. The reporting conditions for conditionally reported observations on the SPOTFIRE R/ST Panel menus are indicated in Table 2.6.1.

Table 2.6.1: Conditional Reporting

Observation Display Name <i>(from Table 2.5.1.1, 2.5.1.2 and/or 2.5.2)</i>	Result Display Name <i>(from Table 2.4.1)</i>	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. <i>e.g., if two Tm values are found for the PCR2 control, only two of the three observations will be sent</i>
		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. <i>e.g., if two Tm values are found for the RNA process control, only two of the three observations will be sent</i>
		Otherwise, the observation is not included in the electronic report.

2.7. 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 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: <ul style="list-style-type: none"> 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 your local bioMerieux subsidiary or distributor.	Present when the Pouch Result is Fail.
PCR Test	Always present.
<p>Edit History: Sample ID changed from {0} to {1} by {2} ({3}) at {4}</p> <p><i>*{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.</i></p>	<p>Present when an operator changes a sample ID after the test finished, and manually sends/resends the run up to the connected information system.</p> <p>WARNING: The {4} DateTime value for this note is formatted irrespective of report type and may not use the same format as other time stamps contained within the respective report. The format used is YYYY-MM-DDThh:mm:ssXOH:OM, where:</p> <ul style="list-style-type: none"> YYYY is the four-digit year MM is the two-digit month of the year DD is the two-digit day of the month T is a fixed constant that separates the date and time hh is the 24-hour representation of the hour mm is the minute ss is the second x is "+" if time is Greenwich Mean Time (GMT) plus offset and "-" if time is GMT minus offset OH = hours offset from GMT OM = minutes offset from GMT
Throat swab as a sample type for Coronavirus SARS-CoV-2 detection may vary by location. Contact your local bioMerieux subsidiary or distributor for details.	Present when the panel menu selected is 'Sore Throat Menu'.
QC Designated Test	
Comment	Reporting Condition
Action: Consult the Interpretation of Results table in Quick Guide.	Present when the QC Result is Fail.
Action: Retest once. If problem persists, contact your local bioMerieux subsidiary or distributor.	Present when the Pouch Result is Fail.
PCR Test	Always present.

3. BIOFIRE® SPOTFIRE® Respiratory/Sore Throat Panel Pouch

v4.0.100: Software Does Not Report Coronavirus SARS-CoV-2 for the Throat Swab Sample Type

WARNING: Because throat swab as a sample type for Coronavirus SARS-CoV-2 detection may vary by location, there are two versions of the BIOFIRE® SPOTFIRE® Respiratory/Sore Throat Panel software associated with the pouch:

- **v4.0.4:** Reports Coronavirus SARS-CoV-2 for the Throat Swab sample type (see Section 2)
- **v4.0.100:** Does not report Coronavirus SARS-CoV-2 for the Throat Swab sample type

Users of this guide should verify the appropriate version used by institution for proper mapping. Contact your local bioMérieux subsidiary or distributor for details.

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.

3.1. 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 3.1.1.

Table 3.1.1: Disposable (Pouch)

Name	Coding System
R/ST Panel	BMX

Note: If utilizing HL7, the Coding System will be prepended with "99" (i.e., 99BMX).

3.2. 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 3.2.1.

WARNING: QC is not currently supported for HL7 or XML.

Table 3.2.1: Universal Order/Service ID (Panel Menu)

Code	Display Name	Coding System
RMS	Respiratory Menu	BMX
STS	Sore Throat Menu	BMX

Note: If utilizing HL7, the Coding System will be prepended with "99" (i.e., 99BMX).

3.3. 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 3.3.1.

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 3.3.1: Associated Sample Type(s)

Code	Display Name	Coding System	Associated Panel Menu(s) <i>(from Table 3.2.1)</i>
NPS	Nasopharyngeal Swab	BMX	Respiratory Menu
THR	Throat Swab	BMX	Sore Throat Menu

Note: If utilizing HL7, the Coding System will be prepended with "99" (i.e., 99BMX).

3.4. SPOTFIRE Respiratory/Sore Throat Panel Possible Panel Results and Result Groupings

The possible results (derived from Table 1.3.1) for the SPOTFIRE R/ST Panel 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/ST Panel menu observations. Refer to sections 3.5 and 3.6 to see which of the possible results each observation on the panel menu may be associated with.

Table 3.4.1: Possible Panel Results

Qualitative Results		
<i>Coding System: BMX (for POCT or XML), 99BMX (for HL7)</i>		
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
IN_PROG	In Progress	400
Quantitative Results		
<i>See representation of quantitative results, based on the supported interface type, in Table 1.3.1.</i>		300

The possible result groups (derived from Table 1.3.2) for the SPOTFIRE R/ST Panel are indicated in Table 3.4.2. Refer to sections 3.5 and 3.6 to see which of the result groups each observation on the panel is associated with.

Table 3.4.2: Possible Panel Result Groups

WARNING: Result groups are only reported for XML and HL7 Group Annotations.

Qualitative Results <i>Coding System: BMX (for POCT or XML), 99BMX (for HL7)</i>		
Code	Display Name	Observation Code Assignment
PNLRSLT	Panel Results	
VIRUSE	Viruses	01
BACTER	Bacteria	02
CNTRLS	Control Results	
QCRSLT	QC Result	

3.5. 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 3.5.1.1: Patient Designated Tests (for Respiratory Menu)
- Table 3.5.1.2: Patient Designated Tests (for Sore Throat Menu)
- Table 3.5.2: QC Designated Tests

WARNING: QC is not currently supported for HL7 or XML.

Table 3.5.1.1: Panel Observations for Patient Designated Tests (for Respiratory Menu)

Run Status Observations					
Coding system: BMX (for POCT or XML), 99BMX (for HL7)					
Result Group Code <small>(from Table 3.4.2)</small>	Result Group Display Name <small>(from Table 3.4.2)</small>	Observation Code	Observation Display Name	Possible Result Number(s) <small>(from Table 3.4.1)</small>	Possible Result Code(s) <small>(from Table 3.4.1)</small>
PNLRSLT	Panel Results	RUN_STAT	Run Status	100	PASS
				200	INV_CF
				201	INV_AB
				202	INV_SE
				203	INV_IE
				204	INV_RI
				205	INV_OC
				400	IN_PROG
Target Observations					
Coding System: BMX (for POCT or XML), 99BMX (for HL7)					
Result Group Code <small>(from Table 3.4.2)</small>	Result Group Display Name <small>(from Table 3.4.2)</small>	Observation Code	Observation Display Name	Possible Result Number(s) <small>(from Table 3.4.1)</small>	Possible Result Code(s) <small>(from Table 3.4.1)</small>
VIRUSE	Viruses	RSSx01001	Adenovirus	1	POS
				2	NEG
		RSSx01002	Coronavirus SARS-CoV-2	1	POS
				2	NEG
		RSSx01003	Coronavirus (seasonal)	1	POS
				2	NEG
		RSSx01004	Human metapneumovirus	1	POS
				2	NEG
		RSSx01005	Human rhinovirus/enterovirus	1	POS

		RSSx01006	Influenza A virus	2	NEG		
				1	POS		
				2	NEG		
		RSSx01007	Influenza A virus A/H1-2009	3	UNCERT		
				1	POS		
		RSSx01008	Influenza A virus A/H3	2	NEG		
				1	POS		
		RSSx01009	Influenza B virus	2	NEG		
				1	POS		
		RSSx01010	Parainfluenza virus	2	NEG		
				1	POS		
		RSSx01011	Respiratory syncytial virus	2	NEG		
				1	POS		
		BACTER	Bacteria	RSSx02001	Bordetella parapertussis	1	POS
						2	NEG
				RSSx02002	Bordetella pertussis	1	POS
2	NEG						
RSSx02003	Chlamydia pneumoniae			1	POS		
				2	NEG		
RSSx02004	Mycoplasma pneumoniae			1	POS		
				2	NEG		
Control Observations							
Coding System: BMX (for POCT or XML), 99BMX (for HL7)							
Result Group Code <i>(from Table 3.4.2)</i>	Result Group Display Name <i>(from Table 3.4.2)</i>	Observation Code	Observation Display Name	Possible Result Number(s) <i>(from Table 3.4.1)</i>	Possible Result Code(s) <i>(from Table 3.4.1)</i>		
CNTRLS	Control Results	PCR2_CTRL	PCR2 Control	100	PASS		
				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		

		RNA_CTRL	RNA Process Control	100	PASS
				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

Note: Possible result values shown in blue will only be sent when the SPOTFIRE System is set to transmit failed run data. Possible result values shown in yellow will only be sent when the SPOTFIRE System is set to transmit start test notifications. Observation values shown in red will only be sent when the SPOTFIRE System is set to transmit control values; however, Control Tm values are only sent for passing runs. These features may be toggled on/off in the SPOTFIRE settings menu.

Table 3.5.1.2: Panel Observations for Patient Designated Tests (for Sore Throat Menu)

Run Status Observations					
Coding system: BMX (for POCT or XML), 99BMX (for HL7)					
Result Group Code <i>(from Table 3.4.2)</i>	Result Group Display Name <i>(from Table 3.4.2)</i>	Observation Code	Observation Display Name	Possible Result Number(s) <i>(from Table 3.4.1)</i>	Possible Result Code(s) <i>(from Table 3.4.1)</i>
PNLRSLT	Panel Results	RUN_STAT	Run Status	100	PASS
				200	INV_CF
				201	INV_AB
				202	INV_SE
				203	INV_IE
				204	INV_RI
				205	INV_OC
				400	IN_PROG
Target Observations					
Coding System: BMX (for POCT or XML), 99BMX (for HL7)					
Result Group Code <i>(from Table 3.4.2)</i>	Result Group Display Name <i>(from Table 3.4.2)</i>	Observation Code	Observation Display Name	Possible Result Number(s) <i>(from Table 3.4.1)</i>	Possible Result Code(s) <i>(from Table 3.4.1)</i>
VIRUSE	Viruses	RSSx01001	Adenovirus	1	POS
				2	NEG
		RSSx01003	Coronavirus (seasonal)	1	POS
				2	NEG
		RSSx01004	Human metapneumovirus	1	POS
				2	NEG
		RSSx01005	Human rhinovirus/enterovirus	1	POS
				2	NEG
		RSSx01006	Influenza A virus	1	POS
				2	NEG
				3	UNCERT
		RSSx01007	Influenza A virus A/H1-2009	1	POS
				2	NEG
		RSSx01008	Influenza A virus A/H3	1	POS
				2	NEG
		RSSx01009	Influenza B virus	1	POS
2	NEG				

		RSSx01010	Parainfluenza virus	1	POS		
				2	NEG		
		RSSx01011	Respiratory syncytial virus	1	POS		
				2	NEG		
		BACTER	Bacteria	RSSx02003	Chlamydia pneumoniae	1	POS
						2	NEG
RSSx02004	Mycoplasma pneumoniae			1	POS		
				2	NEG		
RSSx02005	Streptococcus dysgalactiae (group C/G Strep)			1	POS		
				2	NEG		
RSSx02006	Streptococcus pyogenes (group A Strep)			1	POS		
				2	NEG		
Control Observations							
Coding System: <i>BMX</i> (for POCT or XML), <i>99BMX</i> (for HL7)							
Result Group Code <i>(from Table 3.4.2)</i>	Result Group Display Name <i>(from Table 3.4.2)</i>	Observation Code	Observation Display Name	Possible Result Number(s) <i>(from Table 3.4.1)</i>	Possible Result Code(s) <i>(from Table 3.4.1)</i>		
CNTRLS	Control Results	PCR2_CTRL	PCR2 Control	100	PASS		
				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		
		RNA_CTRL	RNA Process Control	100	PASS		
				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
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Note: Possible result values shown in blue will only be sent when the SPOTFIRE System is set to transmit failed run data. Possible result values shown in yellow will only be sent when the SPOTFIRE System is set to transmit start test notifications. Observation values shown in red will only be sent when the SPOTFIRE System is set to transmit control values; however, Control Tm values are only sent for passing runs. These features may be toggled on/off in the SPOTFIRE settings menu.

Table 3.5.2: Panel Observations for QC Designated Tests

Run Status Observations					
<i>Coding system: BMX (for POCT or XML), 99BMX (for HL7)</i>					
Result Group Code <small>(from Table 3.4.2)</small>	Result Group Display Name <small>(from Table 3.4.2)</small>	Observation Code	Observation Display Name	Possible Result Number(s) <small>(from Table 3.4.1)</small>	Possible Result Code(s) <small>(from Table 3.4.1)</small>
PNLRSLT	Panel Results	RUN_STAT	Run Status	100	PASS
				200	INV_CF
				201	INV_AB
				202	INV_SE
				203	INV_IE
				204	INV_RI
				205	INV_OC
				400	IN_PROG
QC Result Observations					
<i>Coding system: BMX (for POCT or XML), 99BMX (for HL7)</i>					
Result Group Code <small>(from Table 3.4.2)</small>	Result Group Display Name <small>(from Table 3.4.2)</small>	Observation Code	Observation Display Name	Possible Result Number(s) <small>(from Table 3.4.1)</small>	Possible Result Code(s) <small>(from Table 3.4.1)</small>
QCRSLT	QC Result	QC_RSLT	QC Result	100	PASS
				101	FAIL
				102	INVALID
Target Observations					
<i>Coding System: BMX (for POCT or XML), 99BMX (for HL7)</i>					
Result Group Code <small>(from Table 3.4.2)</small>	Result Group Display Name <small>(from Table 3.4.2)</small>	Observation Code	Observation Display Name	Possible Result Number(s) <small>(from Table 3.4.1)</small>	Possible Result Code(s) <small>(from Table 3.4.1)</small>
VIRUSE	Viruses	RSSx01001	Adenovirus	1	POS
				2	NEG
		RSSx01002	Coronavirus SARS-CoV-2	1	POS
				2	NEG
		RSSx01003	Coronavirus (seasonal)	1	POS
				2	NEG
		RSSx01004	Human metapneumovirus	1	POS
				2	NEG

		RSSx01005	Human rhinovirus/enterovirus	1	POS
				2	NEG
		RSSx01006	Influenza A virus	1	POS
				2	NEG
		RSSx01007	Influenza A virus A/H1-2009	1	POS
				2	NEG
		RSSx01008	Influenza A virus A/H3	1	POS
				2	NEG
		RSSx01009	Influenza B virus	1	POS
				2	NEG
		RSSx01010	Parainfluenza virus	1	POS
				2	NEG
		RSSx01011	Respiratory syncytial virus	1	POS
				2	NEG
BACTER	Bacteria	RSSx02001	Bordetella parapertussis	1	POS
				2	NEG
		RSSx02002	Bordetella pertussis	1	POS
				2	NEG
		RSSx02003	Chlamydia pneumoniae	1	POS
				2	NEG
		RSSx02004	Mycoplasma pneumoniae	1	POS
				2	NEG
		RSSx02005	Streptococcus dysgalactiae (group C/G Strep)	1	POS
				2	NEG
		RSSx02006	Streptococcus pyogenes (group A Strep)	1	POS
				2	NEG
Control Observations					
Coding System: BMX (for POCT or XML), 99BMX (for HL7)					
Result Group Code <small>(from Table 3.4.2)</small>	Result Group Display Name <small>(from Table 3.4.2)</small>	Observation Code	Observation Display Name	Possible Result Number(s) <small>(from Table 3.4.1)</small>	Possible Result Code(s) <small>(from Table 3.4.1)</small>
CNTRLS	Control Results	PCR2_CTRL	PCR2 Control	100	PASS
				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
		RNA_CTRL	RNA Process Control	100	PASS
				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

Note: Possible result values shown in blue will only be sent when the SPOTFIRE System is set to transmit failed run data. Possible result values shown in yellow will only be sent when the SPOTFIRE System is set to transmit start test notifications. Observation values shown in red will only be sent when the SPOTFIRE System is set to transmit control values; however, Control Tm values are only sent for passing runs. These features may be toggled on/off in the SPOTFIRE settings menu.

3.6. 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 3.5. The reporting conditions for conditionally reported observations on the SPOTFIRE R/ST Panel menus are indicated in Table 3.6.1.

Table 3.6.1: Conditional Reporting

Observation Display Name <i>(from Table 3.5.1.1, 3.5.1.2 and/or 3.5.2)</i>	Result Display Name <i>(from Table 3.4.1)</i>	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. <i>e.g., if two Tm values are found for the PCR2 control, only two of the three observations will be sent</i>
		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. <i>e.g., if two Tm values are found for the RNA process control, only two of the three observations will be sent</i>
		Otherwise, the observation is not included in the electronic report.

3.7. 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 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: <ul style="list-style-type: none"> • 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 your local bioMerieux subsidiary or distributor.	Present when the Pouch Result is Fail.
PCR Test	Always present.
<p>Edit History: Sample ID changed from {0} to {1} by {2} ({3}) at {4}</p> <p><i>*{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.</i></p>	<p>Present when an operator changes a sample ID after the test finished, and manually sends/resends the run up to the connected information system.</p> <p>WARNING: The {4} DateTime value for this note is formatted irrespective of report type and may not use the same format as other time stamps contained within the respective report. The format used is YYYY-MM-DDThh:mm:ssXOH:OM, where:</p> <ul style="list-style-type: none"> • YYYY is the four-digit year • MM is the two-digit month of the year • DD is the two-digit day of the month • T is a fixed constant that separates the date and time • hh is the 24-hour representation of the hour • mm is the minute • ss is the second • x is "+" if time is Greenwich Mean Time (GMT) plus offset and "-" if time is GMT minus offset • OH = hours offset from GMT • OM = minutes offset from GMT
QC Designated Test	
Comment	Reporting Condition
Action: Consult the Interpretation of Results table in Quick Guide.	Present when the QC Result is Fail.
Action: Retest once. If problem persists, contact your local bioMerieux subsidiary or distributor.	Present when the Pouch Result is Fail.
PCR Test	Always present.

4. 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.

4.1. SPOTFIRE Respiratory Panel Disposable (Pouch)

The SPOTFIRE R 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 Panel	BMX

Note: If utilizing HL7, the Coding System will be prepended with "99" (i.e., 99BMX).

4.2. 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 4.2.1.

WARNING: QC is not currently supported for HL7 or XML.

Table 4.2.1: Universal Order/Service ID (Panel)

Code	Display Name	Coding System
R	Respiratory Panel	BMX

Note: If utilizing HL7, the Coding System will be prepended with "99" (i.e., 99BMX).

4.3. 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 4.3.1.

Table 4.3.1: Associated Sample Type(s)

Code	Display Name	Coding System
NPS	Nasopharyngeal Swab	BMX

Note: If utilizing HL7, the Coding System will be prepended with "99" (i.e., 99BMX).

4.4. SPOTFIRE Respiratory Panel Possible Panel Results and Result Groupings

The possible results (derived from Table 1.3.1) for the SPOTFIRE R 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 Panel observations. Refer to sections 4.5 and 4.6 to see which of the possible results each observation on the panel may be associated with.

Table 4.4.1: Possible Panel Results

Qualitative Results		
<i>Coding System: BMX (for POCT or XML), 99BMX (for HL7)</i>		
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		
<i>See representation of quantitative results, based on the supported interface type, in Table 1.3.1.</i>		300

The possible result groups (derived from Table 1.3.2) for the SPOTFIRE R Panel are indicated in Table 4.4.2. Refer to sections 4.5 and 4.6 to see which of the result groups each observation on the panel is associated with.

Table 4.4.2: Possible Panel Result Groups

WARNING: Result groups are only reported for XML and HL7 Group Annotations.

Qualitative Results		
<i>Coding System: BMX (for POCT or XML), 99BMX (for HL7)</i>		
Code	Display Name	Observation Code Assignment
PNLRSLT	Panel Results	
VIRUSE	Viruses	01
BACTER	Bacteria	02
CNTRLS	Control Results	
QCRSLT	QC Result	

4.5. 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 4.5.1: Patient Designated Tests
- Table 4.5.2: QC Designated Tests
WARNING: QC is not currently supported for HL7 or XML.

Table 4.5.1: Panel Observations for Patient Designated Tests

Run Status Observations					
Coding system: BMX (for POCT or XML), 99BMX (for HL7)					
Result Group Code <small>(from Table 4.4.2)</small>	Result Group Display Name <small>(from Table 4.4.2)</small>	Observation Code	Observation Display Name	Possible Result Number(s) <small>(from Table 4.4.1)</small>	Possible Result Code(s) <small>(from Table 4.4.1)</small>
PNLRSLT	Panel Results	RUN_STAT	Run Status	100	PASS
				200	INV_CF
				201	INV_AB
				202	INV_SE
				203	INV_IE
				204	INV_RI
				205	INV_OC
				400	IN_PROG
Target Observations					
Coding System: BMX (for POCT or XML), 99BMX (for HL7)					
Result Group Code <small>(from Table 4.4.2)</small>	Result Group Display Name <small>(from Table 4.4.2)</small>	Observation Code	Observation Display Name	Possible Result Number(s) <small>(from Table 4.4.1)</small>	Possible Result Code(s) <small>(from Table 4.4.1)</small>
VIRUSE	Viruses	RPx01001	Adenovirus	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		
				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		
		RPx01010	Parainfluenza virus	1	POS		
				2	NEG		
		RPx01011	Respiratory syncytial virus	1	POS		
				2	NEG		
		BACTER	Bacteria	RPx02001	Bordetella parapertussis	1	POS
						2	NEG
RPx02002	Bordetella pertussis			1	POS		
				2	NEG		
RPx02003	Chlamydia pneumoniae			1	POS		
				2	NEG		
RPx02004	Mycoplasma pneumoniae			1	POS		
				2	NEG		
Control Observations							
Coding System: BMX (for POCT or XML), 99BMX (for HL7)							
Result Group Code <i>(from Table 4.4.2)</i>	Result Group Display Name <i>(from Table 4.4.2)</i>	Observation Code	Observation Display Name	Possible Result Number(s) <i>(from Table 4.4.1)</i>	Possible Result Code(s) <i>(from Table 4.4.1)</i>		
CNTRLS	Control Results	PCR2_CTRL	PCR2 Control	100	PASS		
				101	FAIL		
		PCR2C_TM_A	PCR2 Control Tm Value A	300	Quantitative (variable) *see section 4.6 for conditional reporting of this observation		
		PCR2C_TM_B	PCR2 Control Tm Value B	300	Quantitative (variable) *see section 4.6 for conditional reporting of this observation		
		PCR2C_TM_C	PCR2 Control Tm Value C	300	Quantitative (variable) *see section 4.6 for conditional reporting of this observation		
		RNA_CTRL	RNA Process Control	100	PASS		
				101	FAIL		

		RNAC_TM_A	RNA Process Control Tm Value A	300	Quantitative (variable) *see section 4.6 for conditional reporting of this observation
		RNAC_TM_B	RNA Process Control Tm Value B	300	Quantitative (variable) *see section 4.6 for conditional reporting of this observation
		RNAC_TM_C	RNA Process Control Tm Value C	300	Quantitative (variable) *see section 4.6 for conditional reporting of this observation

Note: Possible result values shown in blue will only be sent when the SPOTFIRE System is set to transmit failed run data. Possible result values shown in yellow will only be sent when the SPOTFIRE System is set to transmit start test notifications. Observation values shown in red will only be sent when the SPOTFIRE System is set to transmit control values; however, Control Tm values are only sent for passing runs. These features may be toggled on/off in the SPOTFIRE settings menu.

Table 4.5.2: Panel Observations for QC Designated Tests

Run Status Observations					
<i>Coding system: BMX (for POCT or XML), 99BMX (for HL7)</i>					
Result Group Code <small>(from Table 4.4.2)</small>	Result Group Display Name <small>(from Table 4.4.2)</small>	Observation Code	Observation Display Name	Possible Result Number(s) <small>(from Table 4.4.1)</small>	Possible Result Code(s) <small>(from Table 4.4.1)</small>
PNLRSLT	Panel Results	RUN_STAT	Run Status	100	PASS
				200	INV_CF
				201	INV_AB
				202	INV_SE
				203	INV_IE
				204	INV_RI
				205	INV_OC
				400	IN_PROG
QC Result Observations					
<i>Coding system: BMX (for POCT or XML), 99BMX (for HL7)</i>					
Result Group Code <small>(from Table 4.4.2)</small>	Result Group Display Name <small>(from Table 4.4.2)</small>	Observation Code	Observation Display Name	Possible Result Number(s) <small>(from Table 4.4.1)</small>	Possible Result Code(s) <small>(from Table 4.4.1)</small>
QCRSLT	QC Result	QC_RSLT	QC Result	100	PASS
				101	FAIL
				102	INVALID
Target Observations					
<i>Coding System: BMX (for POCT or XML), 99BMX (for HL7)</i>					
Result Group Code <small>(from Table 4.4.2)</small>	Result Group Display Name <small>(from Table 4.4.2)</small>	Observation Code	Observation Display Name	Possible Result Number(s) <small>(from Table 4.4.1)</small>	Possible Result Code(s) <small>(from Table 4.4.1)</small>
VIRUSE	Viruses	RPx01001	Adenovirus	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
				2	NEG
		RPx01010	Parainfluenza virus	1	POS
				2	NEG
		RPx01011	Respiratory syncytial virus	1	POS
				2	NEG
BACTER	Bacteria	RPx02001	Bordetella parapertussis	1	POS
				2	NEG
		RPx02002	Bordetella pertussis	1	POS
				2	NEG
		RPx02003	Chlamydia pneumoniae	1	POS
				2	NEG
		RPx02004	Mycoplasma pneumoniae	1	POS
				2	NEG
Control Observations					
Coding System: BMX (for POCT or XML), 99BMX (for HL7)					
Result Group Code <i>(from Table 4.4.2)</i>	Result Group Display Name <i>(from Table 4.4.2)</i>	Observation Code	Observation Display Name	Possible Result Number(s) <i>(from Table 4.4.1)</i>	Possible Result Code(s) <i>(from Table 4.4.1)</i>
CNTRLS	Control Results	PCR2_CTRL	PCR2 Control	100	PASS
				101	FAIL
		PCR2C_TM_A	PCR2 Control Tm Value A	300	Quantitative (variable) *see section 4.6 for conditional reporting of this observation
		PCR2C_TM_B	PCR2 Control Tm Value B	300	Quantitative (variable) *see section 4.6 for conditional reporting of this observation

		PCR2C_TM_C	PCR2 Control Tm Value C	300	Quantitative (variable) *see section 4.6 for conditional reporting of this observation
		RNA_CTRL	RNA Process Control	100	PASS
				101	FAIL
		RNAC_TM_A	RNA Process Control Tm Value A	300	Quantitative (variable) *see section 4.6 for conditional reporting of this observation
		RNAC_TM_B	RNA Process Control Tm Value B	300	Quantitative (variable) *see section 4.6 for conditional reporting of this observation
		RNAC_TM_C	RNA Process Control Tm Value C	300	Quantitative (variable) *see section 4.6 for conditional reporting of this observation

Note: Possible result values shown in blue will only be sent when the SPOTFIRE System is set to transmit failed run data. Possible result values shown in yellow will only be sent when the SPOTFIRE System is set to transmit start test notifications. Observation values shown in red will only be sent when the SPOTFIRE System is set to transmit control values; however, Control Tm values are only sent for passing runs. These features may be toggled on/off in the SPOTFIRE settings menu.

4.6. SPOTFIRE Respiratory Panel Observation Conditional Reporting

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

Table 4.6.1: Conditional Reporting

Observation Display Name <i>(from Table 4.5.1 and/or 4.5.2)</i>	Result Display Name <i>(from Table 4.4.1)</i>	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. <i>e.g., if two Tm values are found for the PCR2 control, only two of the three observations will be sent</i>
		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. <i>e.g., if two Tm values are found for the RNA process control, only two of the three observations will be sent</i>
		Otherwise, the observation is not included in the electronic report.

4.7. 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 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: <ul style="list-style-type: none"> 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 your local bioMerieux subsidiary or distributor.	Present when the Pouch Result is Fail.
PCR Test	Always present.
<p>Edit History: Sample ID changed from {0} to {1} by {2} ({3}) at {4}</p> <p><i>*{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.</i></p>	<p>Present when an operator changes a sample ID after the test finished, and manually sends/resends the run up to the connected information system.</p> <p>WARNING: The {4} DateTime value for this note is formatted irrespective of report type and may not use the same format as other time stamps contained within the respective report. The format used is YYYY-MM-DDThh:mm:ssXOH:OM, where:</p> <ul style="list-style-type: none"> YYYY is the four-digit year MM is the two-digit month of the year DD is the two-digit day of the month T is a fixed constant that separates the date and time hh is the 24-hour representation of the hour mm is the minute ss is the second x is "+" if time is Greenwich Mean Time (GMT) <i>plus</i> offset and "-" if time is GMT <i>minus</i> offset OH = hours offset from GMT OM = minutes offset from GMT
QC Designated Test	
Comment	Reporting Condition
Action: Consult the Interpretation of Results table in Quick Guide.	Present when the QC Result is Fail.
Action: Retest once. If problem persists, contact your local bioMerieux subsidiary or distributor.	Present when the Pouch Result is Fail.
PCR Test	Always present.

5. 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.

5.1. 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 5.1.1.

Table 5.1.1: Disposable (Pouch)

Name	Coding System
R Panel Mini	BMX

Note: If utilizing HL7, the Coding System will be prepended with "99" (i.e., 99BMX).

5.2. 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 5.2.1.

WARNING: QC is not currently supported for HL7 or XML.

Table 5.2.1: Universal Order/Service ID (Panel)

Code	Display Name	Coding System
RM	Respiratory Panel Mini	BMX

Note: If utilizing HL7, the Coding System will be prepended with "99" (i.e., 99BMX).

5.3. 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 5.3.1.

Table 5.3.1: Associated Sample Type(s)

Code	Display Name	Coding System
NPS	Nasopharyngeal Swab	BMX

Note: If utilizing HL7, the Coding System will be prepended with "99" (i.e., 99BMX).

5.4. SPOTFIRE Respiratory Panel Mini Possible Panel Results and Result Groupings

The possible results (derived from Table 1.3.1) for the SPOTFIRE R Panel Mini are indicated in Table 5.4.1. Note that not every result in Table 5.4.1 will be associated with all of the SPOTFIRE R Panel Mini observations. Refer to sections 5.5 and 5.6 to see which of the possible results each observation on the panel may be associated with.

Table 5.4.1: Possible Panel Results

Qualitative Results		
<i>Coding System: BMX (for POCT or XML), 99BMX (for HL7)</i>		
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		
<i>See representation of quantitative results, based on the supported interface type, in Table 1.3.1.</i>		300

The possible result groups (derived from Table 1.3.2) for the SPOTFIRE R Panel Mini are indicated in Table 5.4.2. Refer to sections 5.5 and 5.6 to see which of the result groups each observation on the panel is associated with.

Table 5.4.2: Possible Panel Result Groups

WARNING: Result groups are only reported for XML and HL7 Group Annotations.

Qualitative Results		
<i>Coding System: BMX (for POCT or XML), 99BMX (for HL7)</i>		
Code	Display Name	Observation Code Assignment
PNLRSLT	Panel Results	
VIRUSE	Viruses	01
CNTRLS	Control Results	
QCRSLT	QC Result	

5.5. 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 5.5.1: Patient Designated Tests
- Table 5.5.2: QC Designated Tests
WARNING: QC is not currently supported for HL7 or XML.

Table 5.5.1: Panel Observations for Patient Designated Tests

Run Status Observations					
Coding system: BMX (for POCT or XML), 99BMX (for HL7)					
Result Group Code <small>(from Table 5.4.2)</small>	Result Group Display Name <small>(from Table 5.4.2)</small>	Observation Code	Observation Display Name	Possible Result Number(s) <small>(from Table 5.4.1)</small>	Possible Result Code(s) <small>(from Table 5.4.1)</small>
PNLRSLT	Panel Results	RUN_STAT	Run Status	100	PASS
				200	INV_CF
				201	INV_AB
				202	INV_SE
				203	INV_IE
				204	INV_RI
				205	INV_OC
				400	IN_PROG
Target Observations					
Coding System: BMX (for POCT or XML), 99BMX (for HL7)					
Result Group Code <small>(from Table 5.4.2)</small>	Result Group Display Name <small>(from Table 5.4.2)</small>	Observation Code	Observation Display Name	Possible Result Number(s) <small>(from Table 5.4.1)</small>	Possible Result Code(s) <small>(from Table 5.4.1)</small>
VIRUSE	Viruses	RMNx01001	Coronavirus SARS-CoV-2	1	POS
				2	NEG
		RMNx01002	Human rhinovirus	1	POS
				2	NEG
		RMNx01003	Influenza A virus	1	POS
				2	NEG
				3	UNCERT
		RMNx01004	Influenza B virus	1	POS
				2	NEG
		RMNx01005	Respiratory syncytial virus	1	POS
				2	NEG

Control Observations					
Coding System: BMX (for POCT or XML), 99BMX (for HL7)					
Result Group Code <i>(from Table 5.4.2)</i>	Result Group Display Name <i>(from Table 5.4.2)</i>	Observation Code	Observation Display Name	Possible Result Number(s) <i>(from Table 5.4.1)</i>	Possible Result Code(s) <i>(from Table 5.4.1)</i>
CNTRLS	Control Results	PCR2_CTRL	PCR2 Control	100	PASS
				101	FAIL
		PCR2C_TM_A	PCR2 Control Tm Value A	300	Quantitative (variable) *see section 5.6 for conditional reporting of this observation
		PCR2C_TM_B	PCR2 Control Tm Value B	300	Quantitative (variable) *see section 5.6 for conditional reporting of this observation
		PCR2C_TM_C	PCR2 Control Tm Value C	300	Quantitative (variable) *see section 5.6 for conditional reporting of this observation
		RNA_CTRL	RNA Process Control	100	PASS
				101	FAIL
		RNAC_TM_A	RNA Process Control Tm Value A	300	Quantitative (variable) *see section 5.6 for conditional reporting of this observation
		RNAC_TM_B	RNA Process Control Tm Value B	300	Quantitative (variable) *see section 5.6 for conditional reporting of this observation
		RNAC_TM_C	RNA Process Control Tm Value C	300	Quantitative (variable) *see section 5.6 for conditional reporting of this observation

Note: Possible result values shown in blue will only be sent when the SPOTFIRE System is set to transmit failed run data. Possible result values shown in yellow will only be sent when the SPOTFIRE System is set to transmit start test notifications. Observation values shown in red will only be sent when the SPOTFIRE System is set to transmit control values; however, Control Tm values are only sent for passing runs. These features may be toggled on/off in the SPOTFIRE settings menu.

Table 5.5.2: Panel Observations for QC Designated Tests

Run Status Observations					
<i>Coding system: BMX (for POCT or XML), 99BMX (for HL7)</i>					
Result Group Code <small>(from Table 5.4.2)</small>	Result Group Display Name <small>(from Table 5.4.2)</small>	Observation Code	Observation Display Name	Possible Result Number(s) <small>(from Table 5.4.1)</small>	Possible Result Code(s) <small>(from Table 5.4.1)</small>
PNLRSLT	Panel Results	RUN_STAT	Run Status	100	PASS
				200	INV_CF
				201	INV_AB
				202	INV_SE
				203	INV_IE
				204	INV_RI
				205	INV_OC
				400	IN_PROG
QC Result Observations					
<i>Coding system: BMX (for POCT or XML), 99BMX (for HL7)</i>					
Result Group Code <small>(from Table 5.4.2)</small>	Result Group Display Name <small>(from Table 5.4.2)</small>	Observation Code	Observation Display Name	Possible Result Number(s) <small>(from Table 5.4.1)</small>	Possible Result Code(s) <small>(from Table 5.4.1)</small>
QCRSLT	QC Result	QC_RSLT	QC Result	100	PASS
				101	FAIL
				102	INVALID
Target Observations					
<i>Coding System: BMX (for POCT or XML), 99BMX (for HL7)</i>					
Result Group Code <small>(from Table 5.4.2)</small>	Result Group Display Name <small>(from Table 5.4.2)</small>	Observation Code	Observation Display Name	Possible Result Number(s) <small>(from Table 5.4.1)</small>	Possible Result Code(s) <small>(from Table 5.4.1)</small>
VIRUSE	Viruses	RMNx01001	Coronavirus SARS-CoV-2	1	POS
				2	NEG
		RMNx01002	Human rhinovirus	1	POS
				2	NEG
		RMNx01003	Influenza A virus	1	POS
				2	NEG
		RMNx01004	Influenza B virus	1	POS
				2	NEG

		RMNx01005	Respiratory syncytial virus	1	POS
				2	NEG
Control Observations					
Coding System: BMX (for POCT or XML), 99BMX (for HL7)					
Result Group Code <i>(from Table 5.4.2)</i>	Result Group Display Name <i>(from Table 5.4.2)</i>	Observation Code	Observation Display Name	Possible Result Number(s) <i>(from Table 5.4.1)</i>	Possible Result Code(s) <i>(from Table 5.4.1)</i>
CNTRL5	Control Results	PCR2_CTRL	PCR2 Control	100	PASS
				101	FAIL
		PCR2C_TM_A	PCR2 Control Tm Value A	300	Quantitative (variable) *see section 5.6 for conditional reporting of this observation
		PCR2C_TM_B	PCR2 Control Tm Value B	300	Quantitative (variable) *see section 5.6 for conditional reporting of this observation
		PCR2C_TM_C	PCR2 Control Tm Value C	300	Quantitative (variable) *see section 5.6 for conditional reporting of this observation
		RNA_CTRL	RNA Process Control	100	PASS
				101	FAIL
		RNAC_TM_A	RNA Process Control Tm Value A	300	Quantitative (variable) *see section 5.6 for conditional reporting of this observation
		RNAC_TM_B	RNA Process Control Tm Value B	300	Quantitative (variable) *see section 5.6 for conditional reporting of this observation
		RNAC_TM_C	RNA Process Control Tm Value C	300	Quantitative (variable) *see section 5.6 for conditional reporting of this observation

Note: Possible result values shown in blue will only be sent when the SPOTFIRE System is set to transmit failed run data. Possible result values shown in yellow will only be sent when the SPOTFIRE System is set to transmit start test notifications. Observation values shown in red will only be sent when the SPOTFIRE System is set to transmit control values; however, Control Tm values are only sent for passing runs. These features may be toggled on/off in the SPOTFIRE settings menu.

5.6. 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 5.5. The reporting conditions for conditionally reported observations on the SPOTFIRE R Panel Mini are indicated in Table 5.6.1.

Table 5.6.1: Conditional Reporting

Observation Display Name <i>(from Table 5.5.1 and/or 5.5.2)</i>	Result Display Name <i>(from Table 5.4.1)</i>	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. <i>e.g., if two Tm values are found for the PCR2 control, only two of the three observations will be sent</i>
		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. <i>e.g., if two Tm values are found for the RNA process control, only two of the three observations will be sent</i>
		Otherwise, the observation is not included in the electronic report.

5.7. 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 5.7.1.

Table 5.7.1: 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: <ul style="list-style-type: none"> 4+ organisms have positive results an organism(s) has an uncertain result
Action: Retest once. If problem persists, contact your local bioMerieux subsidiary or distributor.	Present when the Pouch Result is Fail.
PCR Test	Always present.
<p>Edit History: Sample ID changed from {0} to {1} by {2} ({3}) at {4}</p> <p><i>*{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.</i></p>	<p>Present when an operator changes a sample ID after the test finished, and manually sends/resends the run up to the connected information system.</p> <p>WARNING: The {4} DateTime value for this note is formatted irrespective of report type and may not use the same format as other time stamps contained within the respective report. The format used is YYYY-MM-DDThh:mm:ssXOH:OM, where:</p> <ul style="list-style-type: none"> YYYY is the four-digit year MM is the two-digit month of the year DD is the two-digit day of the month T is a fixed constant that separates the date and time hh is the 24-hour representation of the hour mm is the minute ss is the second x is "+" if time is Greenwich Mean Time (GMT) plus offset and "-" if time is GMT minus offset OH = hours offset from GMT OM = minutes offset from GMT
QC Designated Test	
Comment	Reporting Condition
Action: Consult the Interpretation of Results table in Quick Guide.	Present when the QC Result is Fail.
Action: Retest once. If problem persists, contact your local bioMerieux subsidiary or distributor.	Present when the Pouch Result is Fail.
PCR Test	Always present.

6. BIOFIRE® SPOTFIRE® Respiratory/Sore Throat Panel Mini Pouch

The BIOFIRE® SPOTFIRE® Respiratory/Sore Throat Panel Mini (referred to as the SPOTFIRE R/ST Panel Mini), run using a SPOTFIRE R/ST 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. The SPOTFIRE R/ST Panel Mini encompasses two test menus, each with a unique set of pathogens: Respiratory Mini and Sore Throat Mini.

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

6.1. SPOTFIRE Respiratory/Sore Throat Panel Mini Disposable (Pouch)

The SPOTFIRE R/ST Panel Mini is run using a pouch as the disposable, whose properties are indicated in Table 6.1.1.

Table 6.1.1: Disposable (Pouch)

Name	Coding System
R/ST Panel Mini	BMX

Note: If utilizing HL7, the Coding System will be prepended with "99" (i.e., 99BMX).

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

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

The panel menu (or test) properties for each panel are indicated in Table 6.2.1.

WARNING: QC is not currently supported for HL7 or XML.

Table 6.2.1: Universal Order/Service ID (Panel Menu)

Code	Display Name	Coding System
RMSM	Respiratory Mini Menu	BMX
STSM	Sore Throat Mini Menu	BMX

Note: If utilizing HL7, the Coding System will be prepended with "99" (i.e., 99BMX).

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

The SPOTFIRE R/ST Panel Mini pouch may be used with a subset of cleared sample type(s), whose properties are indicated in Table 6.3.1.

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 6.3.1: Associated Sample Type(s)

Code	Display Name	Coding System	Associated Panel Menu(s) <i>(from Table 6.2.1)</i>
NAP	Nasal Swab/Nasopharyngeal Swab	BMX	Respiratory Mini Menu
THR	Throat Swab	BMX	Sore Throat Mini Menu

Note: If utilizing HL7, the Coding System will be prepended with "99" (i.e., 99BMX).

6.4. SPOTFIRE Respiratory/Sore Throat Panel Mini Possible Panel Results and Result Groupings

The possible results (derived from Table 1.3.1) for the SPOTFIRE R/ST Panel Mini are indicated in Table 6.4.1. Note that not every result in Table 6.4.1 will be associated with all of the SPOTFIRE R/ST Panel Mini menu observations. Refer to sections 6.5 and 6.6 to see which of the possible results each observation on the panel menu may be associated with.

Table 6.4.1: Possible Panel Results

Qualitative Results		
<i>Coding System: BMX (for POCT or XML), 99BMX (for HL7)</i>		
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
IN_PROG	In Progress	400
Quantitative Results		
<i>See representation of quantitative results, based on the supported interface type, in Table 1.3.1.</i>		300

The possible result groups (derived from Table 1.3.2) for the SPOTFIRE R/ST Panel Mini are indicated in Table 6.4.2. Refer to sections 6.5 and 6.6 to see which of the result groups each observation on the panel is associated with.

Table 6.4.2: Possible Panel Result Groups

WARNING: Result groups are only reported for XML and HL7 Group Annotations.

Qualitative Results <i>Coding System: BMX (for POCT or XML), 99BMX (for HL7)</i>		
Code	Display Name	Observation Code Assignment
PNLRSLT	Panel Results	
VIRUSE	Viruses	01
BACTER	Bacteria	02
CNTRLS	Control Results	
QCRSLT	QC Result	

6.5. SPOTFIRE Respiratory/Sore Throat Panel Mini Possible Panel Observations

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

- Table 6.5.1.1: Patient Designated Tests (for Respiratory Mini Menu)
- Table 6.5.1.2: Patient Designated Tests (for Sore Throat Mini Menu)
- Table 6.5.2: QC Designated Tests

WARNING: QC is not currently supported for HL7 or XML.

Table 6.5.1.1: Panel Observations for Patient Designated Tests (for Respiratory Mini Menu)

Run Status Observations					
Coding system: BMX (for POCT or XML), 99BMX (for HL7)					
Result Group Code <small>(from Table 6.4.2)</small>	Result Group Display Name <small>(from Table 6.4.2)</small>	Observation Code	Observation Display Name	Possible Result Number(s) <small>(from Table 6.4.1)</small>	Possible Result Code(s) <small>(from Table 6.4.1)</small>
PNLRSLT	Panel Results	RUN_STAT	Run Status	100	PASS
				200	INV_CF
				201	INV_AB
				202	INV_SE
				203	INV_IE
				204	INV_RI
				205	INV_OC
				400	IN_PROG
Target Observations					
Coding System: BMX (for POCT or XML), 99BMX (for HL7)					
Result Group Code <small>(from Table 6.4.2)</small>	Result Group Display Name <small>(from Table 6.4.2)</small>	Observation Code	Observation Display Name	Possible Result Number(s) <small>(from Table 6.4.1)</small>	Possible Result Code(s) <small>(from Table 6.4.1)</small>
VIRUSE	Viruses	RSMx01001	Coronavirus SARS-CoV-2	1	POS
				2	NEG
		RSMx01002	Human rhinovirus	1	POS
				2	NEG
		RSMx01003	Influenza A virus	1	POS
				2	NEG
				3	UNCERT
		RSMx01004	Influenza B virus	1	POS
2	NEG				

		RSMx01005	Respiratory syncytial virus	1	POS
				2	NEG
Control Observations					
Coding System: BMX (for POCT or XML), 99BMX (for HL7)					
Result Group Code <i>(from Table 6.4.2)</i>	Result Group Display Name <i>(from Table 6.4.2)</i>	Observation Code	Observation Display Name	Possible Result Number(s) <i>(from Table 6.4.1)</i>	Possible Result Code(s) <i>(from Table 6.4.1)</i>
CNTRLS	Control Results	PCR2_CTRL	PCR2 Control	100	PASS
				101	FAIL
		PCR2C_TM_A	PCR2 Control Tm Value A	300	Quantitative (variable) *see section 6.6 for conditional reporting of this observation
		PCR2C_TM_B	PCR2 Control Tm Value B	300	Quantitative (variable) *see section 6.6 for conditional reporting of this observation
		PCR2C_TM_C	PCR2 Control Tm Value C	300	Quantitative (variable) *see section 6.6 for conditional reporting of this observation
		RNA_CTRL	RNA Process Control	100	PASS
				101	FAIL
		RNAC_TM_A	RNA Process Control Tm Value A	300	Quantitative (variable) *see section 6.6 for conditional reporting of this observation
		RNAC_TM_B	RNA Process Control Tm Value B	300	Quantitative (variable) *see section 6.6 for conditional reporting of this observation
		RNAC_TM_C	RNA Process Control Tm Value C	300	Quantitative (variable) *see section 6.6 for conditional reporting of this observation

Note: Possible result values shown in blue will only be sent when the SPOTFIRE System is set to transmit failed run data. Possible result values shown in yellow will only be sent when the SPOTFIRE System is set to transmit start test notifications. Observation values shown in red will only be sent when the SPOTFIRE System is set to transmit control values; however, Control Tm values are only sent for passing runs. These features may be toggled on/off in the SPOTFIRE settings menu.

Table 6.5.1.2: Panel Observations for Patient Designated Tests (for Sore Throat Mini Menu)

Run Status Observations							
<i>Coding system: BMX (for POCT or XML), 99BMX (for HL7)</i>							
Result Group Code <small>(from Table 6.4.2)</small>	Result Group Display Name <small>(from Table 6.4.2)</small>	Observation Code	Observation Display Name	Possible Result Number(s) <small>(from Table 6.4.1)</small>	Possible Result Code(s) <small>(from Table 6.4.1)</small>		
PNLRSLT	Panel Results	RUN_STAT	Run Status	100	PASS		
				200	INV_CF		
				201	INV_AB		
				202	INV_SE		
				203	INV_IE		
				204	INV_RI		
				205	INV_OC		
				400	IN_PROG		
Target Observations							
<i>Coding System: BMX (for POCT or XML), 99BMX (for HL7)</i>							
Result Group Code <small>(from Table 6.4.2)</small>	Result Group Display Name <small>(from Table 6.4.2)</small>	Observation Code	Observation Display Name	Possible Result Number(s) <small>(from Table 6.4.1)</small>	Possible Result Code(s) <small>(from Table 6.4.1)</small>		
VIRUSE	Viruses	RSMx01002	Human rhinovirus	1	POS		
				2	NEG		
		RSMx01003	Influenza A virus	1	POS		
				2	NEG		
				3	UNCERT		
		RSMx01004	Influenza B virus	1	POS		
				2	NEG		
		RSMx01005	Respiratory syncytial virus	1	POS		
				2	NEG		
		BACTER	Bacteria	RSMx02001	Streptococcus pyogenes (group A Strep)	1	POS
						2	NEG
		Control Observations					
<i>Coding System: BMX (for POCT or XML), 99BMX (for HL7)</i>							

Result Group Code <i>(from Table 6.4.2)</i>	Result Group Display Name <i>(from Table 6.4.2)</i>	Observation Code	Observation Display Name	Possible Result Number(s) <i>(from Table 6.4.1)</i>	Possible Result Code(s) <i>(from Table 6.4.1)</i>
CNTRLS	Control Results	PCR2_CTRL	PCR2 Control	100	PASS
				101	FAIL
		PCR2C_TM_A	PCR2 Control Tm Value A	300	Quantitative (variable) *see section 6.6 for conditional reporting of this observation
		PCR2C_TM_B	PCR2 Control Tm Value B	300	Quantitative (variable) *see section 6.6 for conditional reporting of this observation
		PCR2C_TM_C	PCR2 Control Tm Value C	300	Quantitative (variable) *see section 6.6 for conditional reporting of this observation
		RNA_CTRL	RNA Process Control	100	PASS
				101	FAIL
		RNAC_TM_A	RNA Process Control Tm Value A	300	Quantitative (variable) *see section 6.6 for conditional reporting of this observation
RNAC_TM_B	RNA Process Control Tm Value B	300	Quantitative (variable) *see section 6.6 for conditional reporting of this observation		
RNAC_TM_C	RNA Process Control Tm Value C	300	Quantitative (variable) *see section 6.6 for conditional reporting of this observation		

Note: Possible result values shown in blue will only be sent when the SPOTFIRE System is set to transmit failed run data. Possible result values shown in yellow will only be sent when the SPOTFIRE System is set to transmit start test notifications. Observation values shown in red will only be sent when the SPOTFIRE System is set to transmit control values; however, Control Tm values are only sent for passing runs. These features may be toggled on/off in the SPOTFIRE settings menu.

Table 6.5.2: Panel Observations for QC Designated Tests

Run Status Observations					
<i>Coding system: BMX (for POCT or XML), 99BMX (for HL7)</i>					
Result Group Code <small>(from Table 6.4.2)</small>	Result Group Display Name <small>(from Table 6.4.2)</small>	Observation Code	Observation Display Name	Possible Result Number(s) <small>(from Table 6.4.1)</small>	Possible Result Code(s) <small>(from Table 6.4.1)</small>
PNLRSLT	Panel Results	RUN_STAT	Run Status	100	PASS
				200	INV_CF
				201	INV_AB
				202	INV_SE
				203	INV_IE
				204	INV_RI
				205	INV_OC
				400	IN_PROG
QC Result Observations					
<i>Coding system: BMX (for POCT or XML), 99BMX (for HL7)</i>					
Result Group Code <small>(from Table 6.4.2)</small>	Result Group Display Name <small>(from Table 6.4.2)</small>	Observation Code	Observation Display Name	Possible Result Number(s) <small>(from Table 6.4.1)</small>	Possible Result Code(s) <small>(from Table 6.4.1)</small>
QCRSLT	QC Result	QC_RSLT	QC Result	100	PASS
				101	FAIL
				102	INVALID
Target Observations					
<i>Coding System: BMX (for POCT or XML), 99BMX (for HL7)</i>					
Result Group Code <small>(from Table 6.4.2)</small>	Result Group Display Name <small>(from Table 6.4.2)</small>	Observation Code	Observation Display Name	Possible Result Number(s) <small>(from Table 6.4.1)</small>	Possible Result Code(s) <small>(from Table 6.4.1)</small>
VIRUSE	Viruses	RSMx01001	Coronavirus SARS-CoV-2	1	POS
				2	NEG
		RSMx01002	Human rhinovirus	1	POS
				2	NEG
		RSMx01003	Influenza A virus	1	POS
				2	NEG
		RSMx01004	Influenza B virus	1	POS
				2	NEG

BACTER	Bacteria	RSMx01005	Respiratory syncytial virus	1	POS
				2	NEG
		RSMx02001	Streptococcus pyogenes (group A Strep)	1	POS
				2	NEG
Control Observations					
Coding System: BMX (for POCT or XML), 99BMX (for HL7)					
Result Group Code <i>(from Table 6.4.2)</i>	Result Group Display Name <i>(from Table 6.4.2)</i>	Observation Code	Observation Display Name	Possible Result Number(s) <i>(from Table 6.4.1)</i>	Possible Result Code(s) <i>(from Table 6.4.1)</i>
CNTRLs	Control Results	PCR2_CTRL	PCR2 Control	100	PASS
				101	FAIL
		PCR2C_TM_A	PCR2 Control Tm Value A	300	Quantitative (variable) *see section 6.6 for conditional reporting of this observation
		PCR2C_TM_B	PCR2 Control Tm Value B	300	Quantitative (variable) *see section 6.6 for conditional reporting of this observation
		PCR2C_TM_C	PCR2 Control Tm Value C	300	Quantitative (variable) *see section 6.6 for conditional reporting of this observation
		RNA_CTRL	RNA Process Control	100	PASS
				101	FAIL
		RNAC_TM_A	RNA Process Control Tm Value A	300	Quantitative (variable) *see section 6.6 for conditional reporting of this observation
		RNAC_TM_B	RNA Process Control Tm Value B	300	Quantitative (variable) *see section 6.6 for conditional reporting of this observation
		RNAC_TM_C	RNA Process Control Tm Value C	300	Quantitative (variable) *see section 6.6 for conditional reporting of this observation

Note: Possible result values shown in blue will only be sent when the SPOTFIRE System is set to transmit failed run data. Possible result values shown in yellow will only be sent when the SPOTFIRE System is set to transmit start test notifications. Observation values shown in red will only be sent when the SPOTFIRE System is set to transmit control values; however, Control Tm values are only sent for passing runs. These features may be toggled on/off in the SPOTFIRE settings menu.

6.6. SPOTFIRE Respiratory/Sore Throat Panel Mini Observation Conditional Reporting

Some observations on the SPOTFIRE R/ST Panel Mini menus are conditionally reported on the electronic report, as indicated in section 6.5. The reporting conditions for conditionally reported observations on the SPOTFIRE R/ST Panel Mini menus are indicated in Table 6.6.1.

Table 6.6.1: Conditional Reporting

Observation Display Name <i>(from Table 6.5.1.1, 6.5.1.2 and/or 6.5.2)</i>	Result Display Name <i>(from Table 6.4.1)</i>	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. <i>e.g., if two Tm values are found for the PCR2 control, only two of the three observations will be sent</i>
		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. <i>e.g., if two Tm values are found for the RNA process control, only two of the three observations will be sent</i>
		Otherwise, the observation is not included in the electronic report.

6.7. SPOTFIRE Respiratory/Sore Throat Panel Mini Warnings and Notes

The SPOTFIRE R/ST 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 6.7.1.

Table 6.7.1: 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: <ul style="list-style-type: none"> 4+ organisms have positive results an organism(s) has an uncertain result
Action: Retest once. If problem persists, contact your local bioMerieux subsidiary or distributor.	Present when the Pouch Result is Fail.
PCR Test	Always present.
<p>Edit History: Sample ID changed from {0} to {1} by {2} ({3}) at {4}</p> <p><i>*{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.</i></p>	<p>Present when an operator changes a sample ID after the test finished, and manually sends/resends the run up to the connected information system.</p> <p>WARNING: The {4} DateTime value for this note is formatted irrespective of report type and may not use the same format as other time stamps contained within the respective report. The format used is YYYY-MM-DDThh:mm:ssXOH:OM, where:</p> <ul style="list-style-type: none"> YYYY is the four-digit year MM is the two-digit month of the year DD is the two-digit day of the month T is a fixed constant that separates the date and time hh is the 24-hour representation of the hour mm is the minute ss is the second x is "+" if time is Greenwich Mean Time (GMT) <i>plus</i> offset and "-" if time is GMT <i>minus</i> offset OH = hours offset from GMT OM = minutes offset from GMT
QC Designated Test	
Comment	Reporting Condition
Action: Consult the Interpretation of Results table in Quick Guide.	Present when the QC Result is Fail.
Action: Retest once. If problem persists, contact your local bioMerieux subsidiary or distributor.	Present when the Pouch Result is Fail.
PCR Test	Always present.

7. BIOFIRE® SPOTFIRE® Respiratory/Sore Throat *plus* Panel Pouch

The BIOFIRE® SPOTFIRE® Respiratory/Sore Throat *plus* Panel (referred to as the SPOTFIRE R/ST*plus* Panel), run using a SPOTFIRE R/ST*plus* Panel pouch, is used for the simultaneous, qualitative detection and identification of multiple respiratory viral and bacterial nucleic acids in nasopharyngeal swab specimens obtained from individuals with signs and symptoms of respiratory tract infection, including COVID-19; (Respiratory *plus* menu) or in throat swab specimens from individuals with signs and symptoms of pharyngitis (Sore Throat *plus* menu).

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

7.1. SPOTFIRE Respiratory/Sore Throat *plus* Panel Disposable (Pouch)

The SPOTFIRE R/ST*plus* Panel is run using a pouch as the disposable, whose properties are indicated in Table 7.1.1.

Table 7.1.1: Disposable (Pouch)

Name	Coding System
R/ST <i>plus</i> Panel	BMX

Note: If utilizing HL7, the Coding System will be prepended with "99" (i.e., 99BMX).

7.2. SPOTFIRE Respiratory/Sore Throat *plus* Panel Universal Order/Service ID (Panel)

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

The panel menu (or test) properties for each panel are indicated in Table 7.2.1.

WARNING: QC is not currently supported for HL7 or XML.

Table 7.2.1: Universal Order/Service ID (Panel Menu)

Code	Display Name	Coding System
RMB	Respiratory <i>plus</i> Menu	BMX
STB	Sore Throat <i>plus</i> Menu	BMX

Note: If utilizing HL7, the Coding System will be prepended with "99" (i.e., 99BMX).

7.3. SPOTFIRE Respiratory/Sore Throat *plus* Panel Associated Sample Type(s)

The SPOTFIRE R/ST*plus* Panel pouch may be used with a subset of cleared sample type(s), whose properties are indicated in Table 7.3.1.

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 7.3.1: Associated Sample Type(s)

Code	Display Name	Coding System	Associated Panel Menu(s) <i>(from Table 7.2.1)</i>
NPS	Nasopharyngeal Swab	BMX	Respiratory plus Menu
THR	Throat Swab	BMX	Sore Throat plus Menu

Note: If utilizing HL7, the Coding System will be prepended with "99" (i.e., 99BMX).

7.4. SPOTFIRE Respiratory/Sore Throat *plus* Panel Possible Panel Results and Result Groupings

The possible results (derived from Table 1.3.1) for the SPOTFIRE R/ST*plus* Panel are indicated in Table 7.4.1. Note that not every result in Table 7.4.1 will be associated with all of the SPOTFIRE R/ST*plus* Panel menu observations. Refer to sections 7.5 and 7.6 to see which of the possible results each observation on the panel menu may be associated with.

Table 7.4.1: Possible Panel Results

Qualitative Results		
<i>Coding System: BMX (for POCT or XML), 99BMX (for HL7)</i>		
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
IN_PROG	In Progress	400
Quantitative Results		
<i>See representation of quantitative results, based on the supported interface type, in Table 1.3.1.</i>		300

The possible result groups (derived from Table 1.3.2) for the SPOTFIRE R/ST*plus* Panel are indicated in Table 7.4.2. Refer to sections 7.5 and 7.6 to see which of the result groups each observation on the panel is associated with.

Table 7.4.2: Possible Panel Result Groups

WARNING: Result groups are only reported for XML and HL7 Group Annotations.

Qualitative Results <i>Coding System: BMX (for POCT or XML), 99BMX (for HL7)</i>		
Code	Display Name	Observation Code Assignment
PNLRSLT	Panel Results	
VIRUSE	Viruses	01
BACTER	Bacteria	02
CNTRLS	Control Results	
QCRSLT	QC Result	

7.5. SPOTFIRE Respiratory/Sore Throat *plus* Panel Possible Panel Observations

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

- Table 7.5.1.1: Patient Designated Tests (for Respiratory *plus* Menu)
- Table 7.5.1.2: Patient Designated Tests (for Sore Throat *plus* Menu)
- Table 7.5.2: QC Designated Tests

WARNING: QC is not currently supported for HL7 or XML.

Table 7.5.1.1: Panel Observations for Patient Designated Tests (for Respiratory *plus* Menu)

Run Status Observations					
Coding system: BMX (for POCT or XML), 99BMX (for HL7)					
Result Group Code <small>(from Table 7.4.2)</small>	Result Group Display Name <small>(from Table 7.4.2)</small>	Observation Code	Observation Display Name	Possible Result Number(s) <small>(from Table 7.4.1)</small>	Possible Result Code(s) <small>(from Table 7.4.1)</small>
PNLRSLT	Panel Results	RUN_STAT	Run Status	100	PASS
				200	INV_CF
				201	INV_AB
				202	INV_SE
				203	INV_IE
				204	INV_RI
				205	INV_OC
				400	IN_PROG
Target Observations					
Coding System: BMX (for POCT or XML), 99BMX (for HL7)					
Result Group Code <small>(from Table 7.4.2)</small>	Result Group Display Name <small>(from Table 7.4.2)</small>	Observation Code	Observation Display Name	Possible Result Number(s) <small>(from Table 7.4.1)</small>	Possible Result Code(s) <small>(from Table 7.4.1)</small>
VIRUSE	Viruses	STRx01001	Adenovirus	1	POS
				2	NEG
		STRx01002	Coronavirus SARS-CoV-2	1	POS
				2	NEG
		STRx01003	Coronavirus (seasonal)	1	POS
				2	NEG
		STRx01004	Human metapneumovirus	1	POS
				2	NEG
		STRx01005	Human rhinovirus/enterovirus	1	POS

		STRx01006	Influenza A virus	2	NEG		
				1	POS		
				2	NEG		
				3	UNCERT		
		STRx01007	Influenza A virus A/H1-2009	1	POS		
				2	NEG		
		STRx01008	Influenza A virus A/H3	1	POS		
				2	NEG		
		STRx01009	Influenza B virus	1	POS		
				2	NEG		
		STRx01010	Parainfluenza virus	1	POS		
				2	NEG		
		STRx01011	Respiratory syncytial virus	1	POS		
				2	NEG		
		BACTER	Bacteria	STRx02001	Bordetella parapertussis	1	POS
						2	NEG
STRx02002	Bordetella pertussis			1	POS		
				2	NEG		
STRx02003	Chlamydia pneumoniae			1	POS		
				2	NEG		
STRx02004	Mycoplasma pneumoniae			1	POS		
				2	NEG		
Control Observations							
Coding System: <i>BMX</i> (for POCT or XML), <i>99BMX</i> (for HL7)							
Result Group Code <i>(from Table 7.4.2)</i>	Result Group Display Name <i>(from Table 7.4.2)</i>	Observation Code	Observation Display Name	Possible Result Number(s) <i>(from Table 7.4.1)</i>	Possible Result Code(s) <i>(from Table 7.4.1)</i>		
CNTRLS	Control Results	PCR2_CTRL	PCR2 Control	100	PASS		
				101	FAIL		
		PCR2C_TM_A	PCR2 Control Tm Value A	300	Quantitative (variable) *see section 7.6 for conditional reporting of this observation		
		PCR2C_TM_B	PCR2 Control Tm Value B	300	Quantitative (variable) *see section 7.6 for conditional reporting of this observation		
		PCR2C_TM_C	PCR2 Control Tm Value C	300	Quantitative (variable) *see section 7.6 for conditional reporting of this observation		

		RNA_CTRL	RNA Process Control	100	PASS
				101	FAIL
		RNAC_TM_A	RNA Process Control Tm Value A	300	Quantitative (variable) *see section 7.6 for conditional reporting of this observation
		RNAC_TM_B	RNA Process Control Tm Value B	300	Quantitative (variable) *see section 7.6 for conditional reporting of this observation
		RNAC_TM_C	RNA Process Control Tm Value C	300	Quantitative (variable) *see section 7.6 for conditional reporting of this observation

Note: Possible result values shown in blue will only be sent when the SPOTFIRE System is set to transmit failed run data. Possible result values shown in yellow will only be sent when the SPOTFIRE System is set to transmit start test notifications. Observation values shown in red will only be sent when the SPOTFIRE System is set to transmit control values; however, Control Tm values are only sent for passing runs. These features may be toggled on/off in the SPOTFIRE settings menu.

Table 7.5.1.2: Panel Observations for Patient Designated Tests (for Sore Throat *plus* Menu)

Run Status Observations					
Coding system: BMX (for POCT or XML), 99BMX (for HL7)					
Result Group Code <i>(from Table 7.4.2)</i>	Result Group Display Name <i>(from Table 7.4.2)</i>	Observation Code	Observation Display Name	Possible Result Number(s) <i>(from Table 7.4.1)</i>	Possible Result Code(s) <i>(from Table 7.4.1)</i>
PNLRSLT	Panel Results	RUN_STAT	Run Status	100	PASS
				200	INV_CF
				201	INV_AB
				202	INV_SE
				203	INV_IE
				204	INV_RI
				205	INV_OC
				400	IN_PROG
Target Observations					
Coding System: BMX (for POCT or XML), 99BMX (for HL7)					
Result Group Code <i>(from Table 7.4.2)</i>	Result Group Display Name <i>(from Table 7.4.2)</i>	Observation Code	Observation Display Name	Possible Result Number(s) <i>(from Table 7.4.1)</i>	Possible Result Code(s) <i>(from Table 7.4.1)</i>
VIRUSE	Viruses	STRx01001	Adenovirus	1	POS
				2	NEG
		STRx01002	Coronavirus SARS-CoV-2	1	POS
				2	NEG
		STRx01003	Coronavirus (seasonal)	1	POS
				2	NEG
		STRx01004	Human metapneumovirus	1	POS
				2	NEG
		STRx01005	Human rhinovirus/enterovirus	1	POS
				2	NEG
		STRx01006	Influenza A virus	1	POS
				2	NEG
				3	UNCERT
		STRx01007	Influenza A virus A/H1-2009	1	POS
				2	NEG
		STRx01008	Influenza A virus A/H3	1	POS
2	NEG				

		STRx01009	Influenza B virus	1	POS
				2	NEG
		STRx01010	Parainfluenza virus	1	POS
				2	NEG
		STRx01011	Respiratory syncytial virus	1	POS
				2	NEG
BACTER	Bacteria	STRx02003	Chlamydia pneumoniae	1	POS
				2	NEG
		STRx02004	Mycoplasma pneumoniae	1	POS
				2	NEG
		STRx02005	Streptococcus dysgalactiae (group C/G Strep)	1	POS
				2	NEG
		STRx02006	Streptococcus pyogenes (group A Strep)	1	POS
				2	NEG
Control Observations					
Coding System: BMX (for POCT or XML), 99BMX (for HL7)					
Result Group Code <i>(from Table 7.4.2)</i>	Result Group Display Name <i>(from Table 7.4.2)</i>	Observation Code	Observation Display Name	Possible Result Number(s) <i>(from Table 7.4.1)</i>	Possible Result Code(s) <i>(from Table 7.4.1)</i>
CNTRLS	Control Results	PCR2_CTRL	PCR2 Control	100	PASS
				101	FAIL
		PCR2C_TM_A	PCR2 Control Tm Value A	300	Quantitative (variable) *see section 7.6 for conditional reporting of this observation
		PCR2C_TM_B	PCR2 Control Tm Value B	300	Quantitative (variable) *see section 7.6 for conditional reporting of this observation
		PCR2C_TM_C	PCR2 Control Tm Value C	300	Quantitative (variable) *see section 7.6 for conditional reporting of this observation
		RNA_CTRL	RNA Process Control	100	PASS
				101	FAIL
		RNAC_TM_A	RNA Process Control Tm Value A	300	Quantitative (variable) *see section 7.6 for conditional reporting of this observation
RNAC_TM_B	RNA Process Control Tm Value B	300	Quantitative (variable) *see section 7.6 for conditional reporting of this observation		

			RNAC_TM_C	RNA Process Control Tm Value C	300	Quantitative (variable) *see section 7.6 for conditional reporting of this observation
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Note: Possible result values shown in blue will only be sent when the SPOTFIRE System is set to transmit failed run data. Possible result values shown in yellow will only be sent when the SPOTFIRE System is set to transmit start test notifications. Observation values shown in red will only be sent when the SPOTFIRE System is set to transmit control values; however, Control Tm values are only sent for passing runs. These features may be toggled on/off in the SPOTFIRE settings menu.

Table 7.5.2: Panel Observations for QC Designated Tests

Run Status Observations					
<i>Coding system: BMX (for POCT or XML), 99BMX (for HL7)</i>					
Result Group Code <small>(from Table 7.4.2)</small>	Result Group Display Name <small>(from Table 7.4.2)</small>	Observation Code	Observation Display Name	Possible Result Number(s) <small>(from Table 7.4.1)</small>	Possible Result Code(s) <small>(from Table 7.4.1)</small>
PNLRSLT	Panel Results	RUN_STAT	Run Status	100	PASS
				200	INV_CF
				201	INV_AB
				202	INV_SE
				203	INV_IE
				204	INV_RI
				205	INV_OC
				400	IN_PROG
QC Result Observations					
<i>Coding system: BMX (for POCT or XML), 99BMX (for HL7)</i>					
Result Group Code <small>(from Table 7.4.2)</small>	Result Group Display Name <small>(from Table 7.4.2)</small>	Observation Code	Observation Display Name	Possible Result Number(s) <small>(from Table 7.4.1)</small>	Possible Result Code(s) <small>(from Table 7.4.1)</small>
QCRSLT	QC Result	QC_RSLT	QC Result	100	PASS
				101	FAIL
				102	INVALID
Target Observations					
<i>Coding System: BMX (for POCT or XML), 99BMX (for HL7)</i>					
Result Group Code <small>(from Table 7.4.2)</small>	Result Group Display Name <small>(from Table 7.4.2)</small>	Observation Code	Observation Display Name	Possible Result Number(s) <small>(from Table 7.4.1)</small>	Possible Result Code(s) <small>(from Table 7.4.1)</small>
VIRUSE	Viruses	STRx01001	Adenovirus	1	POS
				2	NEG
		STRx01002	Coronavirus SARS-CoV-2	1	POS
				2	NEG
		STRx01003	Coronavirus (seasonal)	1	POS
				2	NEG
		STRx01004	Human metapneumovirus	1	POS
				2	NEG

		STRx01005	Human rhinovirus/enterovirus	1	POS
				2	NEG
		STRx01006	Influenza A virus	1	POS
				2	NEG
		STRx01007	Influenza A virus A/H1-2009	1	POS
				2	NEG
		STRx01008	Influenza A virus A/H3	1	POS
				2	NEG
		STRx01009	Influenza B virus	1	POS
				2	NEG
		STRx01010	Parainfluenza virus	1	POS
				2	NEG
		STRx01011	Respiratory syncytial virus	1	POS
				2	NEG
BACTER	Bacteria	STRx02001	Bordetella parapertussis	1	POS
				2	NEG
		STRx02002	Bordetella pertussis	1	POS
				2	NEG
		STRx02003	Chlamydia pneumoniae	1	POS
				2	NEG
		STRx02004	Mycoplasma pneumoniae	1	POS
				2	NEG
		STRx02005	Streptococcus dysgalactiae (group C/G Strep)	1	POS
				2	NEG
		STRx02006	Streptococcus pyogenes (group A Strep)	1	POS
				2	NEG
Control Observations					
Coding System: BMX (for POCT or XML), 99BMX (for HL7)					
Result Group Code <i>(from Table 7.4.2)</i>	Result Group Display Name <i>(from Table 7.4.2)</i>	Observation Code	Observation Display Name	Possible Result Number(s) <i>(from Table 7.4.1)</i>	Possible Result Code(s) <i>(from Table 7.4.1)</i>
CNTRLS	Control Results	PCR2_CTRL	PCR2 Control	100	PASS
				101	FAIL
		PCR2C_TM_A	PCR2 Control Tm Value A	300	Quantitative (variable) *see section 7.6 for conditional reporting of this observation

		PCR2C_TM_B	PCR2 Control Tm Value B	300	Quantitative (variable) *see section 7.6 for conditional reporting of this observation
		PCR2C_TM_C	PCR2 Control Tm Value C	300	Quantitative (variable) *see section 7.6 for conditional reporting of this observation
		RNA_CTRL	RNA Process Control	100	PASS
				101	FAIL
		RNAC_TM_A	RNA Process Control Tm Value A	300	Quantitative (variable) *see section 7.6 for conditional reporting of this observation
		RNAC_TM_B	RNA Process Control Tm Value B	300	Quantitative (variable) *see section 7.6 for conditional reporting of this observation
		RNAC_TM_C	RNA Process Control Tm Value C	300	Quantitative (variable) *see section 7.6 for conditional reporting of this observation

Note: Possible result values shown in blue will only be sent when the SPOTFIRE System is set to transmit failed run data. Possible result values shown in yellow will only be sent when the SPOTFIRE System is set to transmit start test notifications. Observation values shown in red will only be sent when the SPOTFIRE System is set to transmit control values; however, Control Tm values are only sent for passing runs. These features may be toggled on/off in the SPOTFIRE settings menu.

7.6. SPOTFIRE Respiratory/Sore Throat *plus* Panel Observation Conditional Reporting

Some observations on the SPOTFIRE R/ST*plus* Panel menus are conditionally reported on the electronic report, as indicated in section 7.5. The reporting conditions for conditionally reported observations on the SPOTFIRE R/ST*plus* Panel menus are indicated in Table 7.6.1.

Table 7.6.1: Conditional Reporting

Observation Display Name <i>(from Table 7.5.1.1, 7.5.1.2 and/or 7.5.2)</i>	Result Display Name <i>(from Table 7.4.1)</i>	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. <i>e.g., if two Tm values are found for the PCR2 control, only two of the three observations will be sent</i>
		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. <i>e.g., if two Tm values are found for the RNA process control, only two of the three observations will be sent</i>
		Otherwise, the observation is not included in the electronic report.

7.7. SPOTFIRE Respiratory/Sore Throat *plus* Panel Warnings and Notes

The SPOTFIRE R/ST*plus* 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 7.7.1.

Table 7.7.1: 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: <ul style="list-style-type: none"> 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 your local bioMerieux subsidiary or distributor.	Present when the Pouch Result is Fail.
PCR Test	Always present.
<p>Edit History: Sample ID changed from {0} to {1} by {2} ({3}) at {4}</p> <p><i>*{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.</i></p>	<p>Present when an operator changes a sample ID after the test finished, and manually sends/resends the run up to the connected information system.</p> <p>WARNING: The {4} DateTime value for this note is formatted irrespective of report type and may not use the same format as other time stamps contained within the respective report. The format used is YYYY-MM-DDThh:mm:ssXOH:OM, where:</p> <ul style="list-style-type: none"> YYYY is the four-digit year MM is the two-digit month of the year DD is the two-digit day of the month T is a fixed constant that separates the date and time hh is the 24-hour representation of the hour mm is the minute ss is the second x is "+" if time is Greenwich Mean Time (GMT) <i>plus</i> offset and "-" if time is GMT <i>minus</i> offset OH = hours offset from GMT OM = minutes offset from GMT
Throat swab as a sample type for Coronavirus SARS-CoV-2 detection may vary by location. Contact your local bioMerieux subsidiary or distributor for details.	Present when the panel menu selected is 'Sore Throat <i>plus</i> Menu'.
QC Designated Test	
Comment	Reporting Condition
Action: Consult the Interpretation of Results table in Quick Guide.	Present when the QC Result is Fail.
Action: Retest once. If problem persists, contact your local bioMerieux subsidiary or distributor.	Present when the Pouch Result is Fail.
PCR Test	Always present.

8. BIOFIRE® SPOTFIRE® Respiratory/Sore Throat *plus* Panel Mini Pouch

The BIOFIRE® SPOTFIRE® Respiratory/Sore Throat *plus* Panel Mini (referred to as the SPOTFIRE R/ST*plus* Panel Mini), run using a SPOTFIRE R/ST*plus* Panel Mini pouch, is used for the simultaneous, qualitative detection and identification of multiple respiratory viral and bacterial nucleic acids in nasopharyngeal swab or anterior nasal swab specimens obtained from individuals with signs and symptoms of respiratory tract infection, including COVID 19; (Respiratory *plus* mini menu) or in throat swab specimens from individuals with signs and symptoms of pharyngitis; (Sore Throat *plus* mini menu).

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

8.1. SPOTFIRE Respiratory/Sore Throat *plus* Panel Mini Disposable (Pouch)

The SPOTFIRE R/ST*plus* Panel Mini is run using a pouch as the disposable, whose properties are indicated in Table 8.1.1.

Table 8.1.1: Disposable (Pouch)

Name	Coding System
R/ST <i>plus</i> Panel Mini	BMX

Note: If utilizing HL7, the Coding System will be prepended with "99" (i.e., 99BMX).

8.2. SPOTFIRE Respiratory/Sore Throat *plus* Panel Mini Universal Order/Service ID (Panel)

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

The panel menu (or test) properties for each panel are indicated in Table 8.2.1.

WARNING: QC is not currently supported for HL7 or XML.

Table 8.2.1: Universal Order/Service ID (Panel Menu)

Code	Display Name	Coding System
RMIP	Respiratory <i>plus</i> Mini Menu	BMX
STMIP	Sore Throat <i>plus</i> Mini Menu	BMX

Note: If utilizing HL7, the Coding System will be prepended with "99" (i.e., 99BMX).

8.3. SPOTFIRE Respiratory/Sore Throat *plus* Panel Mini Associated Sample Type(s)

The SPOTFIRE R/ST*plus* Panel Mini pouch may be used with a subset of cleared sample type(s), whose properties are indicated in Table 8.3.1.

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 8.3.1: Associated Sample Type(s)

Code	Display Name	Coding System	Associated Panel Menu(s) <i>(from Table 8.2.1)</i>
NAP	Nasal Swab/Nasopharyngeal Swab	BMX	Respiratory plus Mini Menu
THR	Throat Swab	BMX	Sore Throat plus Mini Menu

Note: If utilizing HL7, the Coding System will be prepended with "99" (i.e., 99BMX).

8.4. SPOTFIRE Respiratory/Sore Throat *plus* Panel Mini Possible Panel Results and Result Groupings

The possible results (derived from Table 1.3.1) for the SPOTFIRE R/ST*plus* Panel Mini are indicated in Table 8.4.1. Note that not every result in Table 8.4.1 will be associated with all of the SPOTFIRE R/ST*plus* Panel Mini menu observations. Refer to sections 8.5 and 8.6 to see which of the possible results each observation on the panel menu may be associated with.

Table 8.4.1: Possible Panel Results

Qualitative Results		
<i>Coding System: BMX (for POCT or XML), 99BMX (for HL7)</i>		
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
IN_PROG	In Progress	400
Quantitative Results		
<i>See representation of quantitative results, based on the supported interface type, in Table 1.3.1.</i>		300

The possible result groups (derived from Table 1.3.2) for the SPOTFIRE R/ST*plus* Panel Mini are indicated in Table 8.4.2. Refer to sections 8.5 and 8.6 to see which of the result groups each observation on the panel is associated with.

Table 8.4.2: Possible Panel Result Groups

WARNING: Result groups are only reported for XML and HL7 Group Annotations.

Qualitative Results		
<i>Coding System: BMX (for POCT or XML), 99BMX (for HL7)</i>		
Code	Display Name	Observation Code Assignment
PNLRSLT	Panel Results	
VIRUSE	Viruses	01
BACTER	Bacteria	02
CNTRLS	Control Results	
QCRSLT	QC Result	

8.5. SPOTFIRE Respiratory/Sore Throat *plus* Panel Mini Possible Panel Observations

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

- Table 8.5.1.1: Patient Designated Tests (for Respiratory *plus* Mini Menu)
- Table 8.5.1.2: Patient Designated Tests (for Sore Throat *plus* Mini Menu)
- Table 8.5.2: QC Designated Tests

WARNING: QC is not currently supported for HL7 or XML.

Table 8.5.1.1: Panel Observations for Patient Designated Tests (for Respiratory *plus* Mini Menu)

Run Status Observations					
Coding system: BMX (for POCT or XML), 99BMX (for HL7)					
Result Group Code <small>(from Table 8.4.2)</small>	Result Group Display Name <small>(from Table 8.4.2)</small>	Observation Code	Observation Display Name	Possible Result Number(s) <small>(from Table 8.4.1)</small>	Possible Result Code(s) <small>(from Table 8.4.1)</small>
PNLRSLT	Panel Results	RUN_STAT	Run Status	100	PASS
				200	INV_CF
				201	INV_AB
				202	INV_SE
				203	INV_IE
				204	INV_RI
				205	INV_OC
				400	IN_PROG
Target Observations					
Coding System: BMX (for POCT or XML), 99BMX (for HL7)					
Result Group Code <small>(from Table 8.4.2)</small>	Result Group Display Name <small>(from Table 8.4.2)</small>	Observation Code	Observation Display Name	Possible Result Number(s) <small>(from Table 8.4.1)</small>	Possible Result Code(s) <small>(from Table 8.4.1)</small>
VIRUSE	Viruses	RPMx01001	Coronavirus SARS-CoV-2	1	POS
				2	NEG
		RPMx01002	Human rhinovirus/enterovirus	1	POS
				2	NEG
		RPMx01003	Influenza A virus	1	POS
				2	NEG
				3	UNCERT
		RPMx01004	Influenza B virus	1	POS
2	NEG				

		RPMx01005	Respiratory syncytial virus	1	POS
				2	NEG
Control Observations					
Coding System: BMX (for POCT or XML), 99BMX (for HL7)					
Result Group Code <i>(from Table 8.4.2)</i>	Result Group Display Name <i>(from Table 8.4.2)</i>	Observation Code	Observation Display Name	Possible Result Number(s) <i>(from Table 8.4.1)</i>	Possible Result Code(s) <i>(from Table 8.4.1)</i>
CNTRL5	Control Results	PCR2_CTRL	PCR2 Control	100	PASS
				101	FAIL
		PCR2C_TM_A	PCR2 Control Tm Value A	300	Quantitative (variable) *see section 8.6 for conditional reporting of this observation
		PCR2C_TM_B	PCR2 Control Tm Value B	300	Quantitative (variable) *see section 8.6 for conditional reporting of this observation
		PCR2C_TM_C	PCR2 Control Tm Value C	300	Quantitative (variable) *see section 8.6 for conditional reporting of this observation
		RNA_CTRL	RNA Process Control	100	PASS
				101	FAIL
		RNAC_TM_A	RNA Process Control Tm Value A	300	Quantitative (variable) *see section 8.6 for conditional reporting of this observation
		RNAC_TM_B	RNA Process Control Tm Value B	300	Quantitative (variable) *see section 8.6 for conditional reporting of this observation
		RNAC_TM_C	RNA Process Control Tm Value C	300	Quantitative (variable) *see section 8.6 for conditional reporting of this observation

Note: Possible result values shown in blue will only be sent when the SPOTFIRE System is set to transmit failed run data. Possible result values shown in yellow will only be sent when the SPOTFIRE System is set to transmit start test notifications. Observation values shown in red will only be sent when the SPOTFIRE System is set to transmit control values; however, Control Tm values are only sent for passing runs. These features may be toggled on/off in the SPOTFIRE settings menu.

Table 8.5.1.2: Panel Observations for Patient Designated Tests (for Sore Throat *plus* Mini Menu)

Run Status Observations					
Coding system: BMX (for POCT or XML), 99BMX (for HL7)					
Result Group Code <small>(from Table 8.4.2)</small>	Result Group Display Name <small>(from Table 8.4.2)</small>	Observation Code	Observation Display Name	Possible Result Number(s) <small>(from Table 8.4.1)</small>	Possible Result Code(s) <small>(from Table 8.4.1)</small>
PNLRSLT	Panel Results	RUN_STAT	Run Status	100	PASS
				200	INV_CF
				201	INV_AB
				202	INV_SE
				203	INV_IE
				204	INV_RI
				205	INV_OC
				400	IN_PROG
Target Observations					
Coding System: BMX (for POCT or XML), 99BMX (for HL7)					
Result Group Code <small>(from Table 8.4.2)</small>	Result Group Display Name <small>(from Table 8.4.2)</small>	Observation Code	Observation Display Name	Possible Result Number(s) <small>(from Table 8.4.1)</small>	Possible Result Code(s) <small>(from Table 8.4.1)</small>
VIRUSE	Viruses	RPMx01001	Coronavirus SARS-CoV-2	1	POS
				2	NEG
		RPMx01002	Human rhinovirus/enterovirus	1	POS
				2	NEG
		RPMx01003	Influenza A virus	1	POS
				2	NEG
				3	UNCERT
		RPMx01004	Influenza B virus	1	POS
				2	NEG
		RPMx01005	Respiratory syncytial virus	1	POS
2	NEG				
BACTER	Bacteria	RPMx02001	Streptococcus pyogenes (group A Strep)	1	POS
				2	NEG
Control Observations					
Coding System: BMX (for POCT or XML), 99BMX (for HL7)					

Result Group Code <i>(from Table 8.4.2)</i>	Result Group Display Name <i>(from Table 8.4.2)</i>	Observation Code	Observation Display Name	Possible Result Number(s) <i>(from Table 8.4.1)</i>	Possible Result Code(s) <i>(from Table 8.4.1)</i>
CNTRLS	Control Results	PCR2_CTRL	PCR2 Control	100	PASS
				101	FAIL
		PCR2C_TM_A	PCR2 Control Tm Value A	300	Quantitative (variable) *see section 8.6 for conditional reporting of this observation
		PCR2C_TM_B	PCR2 Control Tm Value B	300	Quantitative (variable) *see section 8.6 for conditional reporting of this observation
		PCR2C_TM_C	PCR2 Control Tm Value C	300	Quantitative (variable) *see section 8.6 for conditional reporting of this observation
		RNA_CTRL	RNA Process Control	100	PASS
				101	FAIL
		RNAC_TM_A	RNA Process Control Tm Value A	300	Quantitative (variable) *see section 8.6 for conditional reporting of this observation
RNAC_TM_B	RNA Process Control Tm Value B	300	Quantitative (variable) *see section 8.6 for conditional reporting of this observation		
RNAC_TM_C	RNA Process Control Tm Value C	300	Quantitative (variable) *see section 8.6 for conditional reporting of this observation		

Note: Possible result values shown in blue will only be sent when the SPOTFIRE System is set to transmit failed run data. Possible result values shown in yellow will only be sent when the SPOTFIRE System is set to transmit start test notifications. Observation values shown in red will only be sent when the SPOTFIRE System is set to transmit control values; however, Control Tm values are only sent for passing runs. These features may be toggled on/off in the SPOTFIRE settings menu.

Table 8.5.2: Panel Observations for QC Designated Tests

Run Status Observations					
<i>Coding system: BMX (for POCT or XML), 99BMX (for HL7)</i>					
Result Group Code <small>(from Table 8.4.2)</small>	Result Group Display Name <small>(from Table 8.4.2)</small>	Observation Code	Observation Display Name	Possible Result Number(s) <small>(from Table 8.4.1)</small>	Possible Result Code(s) <small>(from Table 8.4.1)</small>
PNLRSLT	Panel Results	RUN_STAT	Run Status	100	PASS
				200	INV_CF
				201	INV_AB
				202	INV_SE
				203	INV_IE
				204	INV_RI
				205	INV_OC
				400	IN_PROG
QC Result Observations					
<i>Coding system: BMX (for POCT or XML), 99BMX (for HL7)</i>					
Result Group Code <small>(from Table 8.4.2)</small>	Result Group Display Name <small>(from Table 8.4.2)</small>	Observation Code	Observation Display Name	Possible Result Number(s) <small>(from Table 8.4.1)</small>	Possible Result Code(s) <small>(from Table 8.4.1)</small>
QCRSLT	QC Result	QC_RSLT	QC Result	100	PASS
				101	FAIL
				102	INVALID
Target Observations					
<i>Coding System: BMX (for POCT or XML), 99BMX (for HL7)</i>					
Result Group Code <small>(from Table 8.4.2)</small>	Result Group Display Name <small>(from Table 8.4.2)</small>	Observation Code	Observation Display Name	Possible Result Number(s) <small>(from Table 8.4.1)</small>	Possible Result Code(s) <small>(from Table 8.4.1)</small>
VIRUSE	Viruses	RPMx01001	Coronavirus SARS-CoV-2	1	POS
				2	NEG
		RPMx01002	Human rhinovirus/enterovirus	1	POS
				2	NEG
		RPMx01003	Influenza A virus	1	POS
				2	NEG
		RPMx01004	Influenza B virus	1	POS
				2	NEG

		RPMx01005	Respiratory syncytial virus	1	POS
				2	NEG
BACTER	Bacteria	RPMx02001	Streptococcus pyogenes (group A Strep)	1	POS
				2	NEG
Control Observations					
Coding System: BMX (for POCT or XML), 99BMX (for HL7)					
Result Group Code <i>(from Table 8.4.2)</i>	Result Group Display Name <i>(from Table 8.4.2)</i>	Observation Code	Observation Display Name	Possible Result Number(s) <i>(from Table 8.4.1)</i>	Possible Result Code(s) <i>(from Table 8.4.1)</i>
CNTRLS	Control Results	PCR2_CTRL	PCR2 Control	100	PASS
				101	FAIL
		PCR2C_TM_A	PCR2 Control Tm Value A	300	Quantitative (variable) *see section 8.6 for conditional reporting of this observation
		PCR2C_TM_B	PCR2 Control Tm Value B	300	Quantitative (variable) *see section 8.6 for conditional reporting of this observation
		PCR2C_TM_C	PCR2 Control Tm Value C	300	Quantitative (variable) *see section 8.6 for conditional reporting of this observation
		RNA_CTRL	RNA Process Control	100	PASS
				101	FAIL
		RNAC_TM_A	RNA Process Control Tm Value A	300	Quantitative (variable) *see section 8.6 for conditional reporting of this observation
		RNAC_TM_B	RNA Process Control Tm Value B	300	Quantitative (variable) *see section 8.6 for conditional reporting of this observation
		RNAC_TM_C	RNA Process Control Tm Value C	300	Quantitative (variable) *see section 8.6 for conditional reporting of this observation

Note: Possible result values shown in blue will only be sent when the SPOTFIRE System is set to transmit failed run data. Possible result values shown in yellow will only be sent when the SPOTFIRE System is set to transmit start test notifications. Observation values shown in red will only be sent when the SPOTFIRE System is set to transmit control values; however, Control Tm values are only sent for passing runs. These features may be toggled on/off in the SPOTFIRE settings menu.

8.6. SPOTFIRE Respiratory/Sore Throat *plus* Panel Mini Observation Conditional Reporting

Some observations on the SPOTFIRE R/ST*plus* Panel Mini menus are conditionally reported on the electronic report, as indicated in section 8.5. The reporting conditions for conditionally reported observations on the SPOTFIRE R/ST*plus* Panel Mini menus are indicated in Table 8.6.1.

Table 8.6.1: Conditional Reporting

Observation Display Name <i>(from Table 8.5.1.1, 8.5.1.2 and/or 8.5.2)</i>	Result Display Name <i>(from Table 8.4.1)</i>	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. <i>e.g., if two Tm values are found for the PCR2 control, only two of the three observations will be sent</i>
		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. <i>e.g., if two Tm values are found for the RNA process control, only two of the three observations will be sent</i>
		Otherwise, the observation is not included in the electronic report.

8.7. SPOTFIRE Respiratory/Sore Throat *plus* Panel Mini Warnings and Notes

The SPOTFIRE R/ST*plus* 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 8.7.1.

Table 8.7.1: 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: <ul style="list-style-type: none"> 4+ organisms have positive results an organism(s) has an uncertain result
Action: Retest once. If problem persists, contact your local bioMerieux subsidiary or distributor.	Present when the Pouch Result is Fail.
PCR Test	Always present.
<p>Edit History: Sample ID changed from {0} to {1} by {2} ({3}) at {4}</p> <p><i>*{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.</i></p>	<p>Present when an operator changes a sample ID after the test finished, and manually sends/resends the run up to the connected information system.</p> <p>WARNING: The {4} DateTime value for this note is formatted irrespective of report type and may not use the same format as other time stamps contained within the respective report. The format used is YYYY-MM-DDThh:mm:ssXOH:OM, where:</p> <ul style="list-style-type: none"> YYYY is the four-digit year MM is the two-digit month of the year DD is the two-digit day of the month T is a fixed constant that separates the date and time hh is the 24-hour representation of the hour mm is the minute ss is the second x is "+" if time is Greenwich Mean Time (GMT) <i>plus</i> offset and "-" if time is GMT <i>minus</i> offset OH = hours offset from GMT OM = minutes offset from GMT
Throat swab as a sample type for Coronavirus SARS-CoV-2 detection may vary by location. Contact your local bioMerieux subsidiary or distributor for details.	Present when the panel menu selected is 'Sore Throat <i>plus</i> Mini Menu'.
QC Designated Test	
Comment	Reporting Condition
Action: Consult the Interpretation of Results table in Quick Guide.	Present when the QC Result is Fail.
Action: Retest once. If problem persists, contact your local bioMerieux subsidiary or distributor.	Present when the Pouch Result is Fail.
PCR Test	Always present.

9. 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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