BIOMÉRIEUX

# BIOFIRE® SPOTFIRE® CONNECTIVITY SOFTWARE MAPPING GUIDE

## BIOFIRE® SPOTFIRE® System


PIONEERING DIAGNOSTICS

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# Document Revision History

| Document Number | Revision Description | Release Date |
|---|---|---|
| BFR0001-9777-01 | Initial release of the document. | 04/2023 |

# 1. Using this Document

## 1.1. Purpose

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

## 1.2. Interface Overview

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

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

## 1.3. Mapping by Pouch Type

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

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

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

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

**Table 1.3.1: All Possible Observation Results**

| **Qualitative Results**<br>*Coding System: 99BMX (for HL7 interface) or BMX (for XML interface)* | | |
|---|---|---|
| **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**<br>*Coding system: UCUM* | | |
| | | **Result Number** |
| 71.52° Celsius<br>*Note: 71.52 is displayed for example purposes only. This value will be populated with data from the system.* | | **300** |

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

## 1.4. Interpreting the Table Headers

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

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

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

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

| Color | Panel Name |
|---|---|
| | Respiratory Panel |

# 2. BIOFIRE® SPOTFIRE® Respiratory Panel Pouch

The BIOFIRE® SPOTFIRE® Respiratory Panel (referred to as the SPOTFIRE Respiratory Panel), run using an 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 Respiratory Panel contains information from a single test run using an R Panel pouch.

## 2.1. SPOTFIRE Respiratory Panel Disposable (Pouch)

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

**Table 2.1.1: Disposable (Pouch)**

| Name | Coding System |
|---|---|
| R Panel | BMX |

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

The R Panel pouch is used to test for a panel, which is a syndromic test comprised of multiple pathogens. The panel (or test) properties are indicated in Table 2.2.1.

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

| Code | Display Name | Coding System |
|---|---|---|
| R | Respiratory Panel | BMX |

## 2.3. SPOTFIRE Respiratory Panel Associated Sample Type(s)

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

**Table 2.3.1: Associated Sample Type(s)**

| Code | Display Name | Coding System |
|---|---|---|
| NPS | Nasopharyngeal Swab | BMX |

## 2.4. SPOTFIRE Respiratory Panel Possible Panel Results

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

**Table 2.4.1: Possible Panel Results**

| **Qualitative Results**<br>*Coding System: 99BMX (for HL7 interface) or BMX (for POCT or XML interface)* | | |
|---|---|---|
| **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**<br>*Coding system: UCUM* | | |
| 71.52° Celsius<br>*Note: 71.52 is displayed for example purposes only. This value will be populated with data from the system.* | | **300** |

## 2.5. SPOTFIRE Respiratory Panel Possible Panel Observations

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

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

**Table 2.5.1: Panel Observations for Patient Designated Tests**

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

| **Target Observations**<br>*Coding System: BMX* | | | |
|---|---|---|---|
| **Code** | **Display Name** | **Possible Result Number(s)** *(from Table 2.4.1)* | **Possible Result Code(s)** *(from Table 2.4.1)* |
| RPx01001 | Adenovirus | **1** | POS |
| | | **2** | NEG |
| RPx02001 | *Bordetella parapertussis* | **1** | POS |
| | | **2** | NEG |
| RPx02002 | *Bordetella pertussis* | **1** | POS |
| | | **2** | NEG |
| RPx02003 | *Chlamydia pneumoniae* | **1** | POS |
| | | **2** | NEG |
| RPx01002 | Coronavirus SARS-CoV-2 (COVID-19) | **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 |
| RPx02004 | *Mycoplasma pneumoniae* | **1** | POS |
| | | **2** | NEG |
| RPx01010 | Parainfluenza virus | **1** | POS |
| | | **2** | NEG |
| RPx01011 | Respiratory syncytial virus | **1** | POS |
| | | **2** | NEG |
| **Control Observations**<br>*Coding System: BMX* | | | |

| Code | Display Name | Possible Result Number(s) *(from Table 2.4.1)* | Possible Result Code(s) *(from Table 2.4.1)* |
|---|---|---|---|
| PCR2_CTRL | PCR2 Control | 100 | PASS |
| | | 101 | FAIL |
| PCR2C_TM_A | PCR2 Control Tm Value A | 300 | Quantitative (variable)<br>*see section 2.6 for conditional reporting of this observation |
| PCR2C_TM_B | PCR2 Control Tm Value B | 300 | Quantitative (variable)<br>*see section 2.6 for conditional reporting of this observation |
| PCR2C_TM_C | PCR2 Control Tm Value C | 300 | Quantitative (variable)<br>*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)<br>*see section 2.6 for conditional reporting of this observation |
| RNAC_TM_B | RNA Process Control Tm Value B | 300 | Quantitative (variable)<br>*see section 2.6 for conditional reporting of this observation |
| RNAC_TM_C | RNA Process Control Tm Value C | 300 | Quantitative (variable)<br>*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. 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**<br>*Coding system: BMX* | | | |
|---|---|---|---|
| **Code** | **Display Name** | **Possible Result Number(s)** *(from Table 2.4.1)* | **Possible Result Code(s)** *(from Table 2.4.1)* |
| RUN_STAT | Run Status | 100 | PASS |
| | | 200 | INV_CF |
| | | 201 | INV_AB |
| | | 202 | INV_SE |
| | | 203 | INV_IE |
| | | 204 | INV_RI |
| | | 205 | INV_OC |

**QC Result Observations**
*Coding system: BMX*

| Code | Display Name | Possible Result Number(s) *(from Table 2.4.1)* | Possible Result Code(s) *(from Table 2.4.1)* |
|---|---|---|---|
| QC_RSLT | QC Result | **100** | PASS |
| | | **101** | FAIL |
| | | **102** | INVALID |

**Target Observations**
*Coding System: BMX*

| Code | Display Name | Possible Result Number(s) *(from Table 2.4.1)* | Possible Result Code(s) *(from Table 2.4.1)* |
|---|---|---|---|
| RPx01001 | Adenovirus | **1** | POS |
| | | **2** | NEG |
| RPx02001 | *Bordetella parapertussis* | **1** | POS |
| | | **2** | NEG |
| RPx02002 | *Bordetella pertussis* | **1** | POS |
| | | **2** | NEG |
| RPx02003 | *Chlamydia pneumoniae* | **1** | POS |
| | | **2** | NEG |
| RPx01002 | Coronavirus SARS-CoV-2 (COVID-19) | **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 |

| | | | |
|---|---|---|---|
| RPx02004 | *Mycoplasma pneumoniae* | **1** | POS |
| | | **2** | NEG |
| RPx01010 | Parainfluenza virus | **1** | POS |
| | | **2** | NEG |
| RPx01011 | Respiratory syncytial virus | **1** | POS |
| | | **2** | NEG |
| **Control Observations**<br>*Coding System: BMX* | | | |
| **Code** | **Display Name** | **Possible Result Number(s)** *(from Table 2.4.1)* | **Possible Result Code(s)** *(from Table 2.4.1)* |
| PCR2_CTRL | PCR2 Control | **100** | PASS |
| | | **101** | FAIL |
| PCR2C_TM_A | PCR2 Control Tm Value A | **300** | Quantitative (variable)<br>*see section 2.6 for conditional reporting of this observation |
| PCR2C_TM_B | PCR2 Control Tm Value B | **300** | Quantitative (variable)<br>*see section 2.6 for conditional reporting of this observation |
| PCR2C_TM_C | PCR2 Control Tm Value C | **300** | Quantitative (variable)<br>*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)<br>*see section 2.6 for conditional reporting of this observation |
| RNAC_TM_B | RNA Process Control Tm Value B | **300** | Quantitative (variable)<br>*see section 2.6 for conditional reporting of this observation |
| RNAC_TM_C | RNA Process Control Tm Value C | **300** | Quantitative (variable)<br>*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. 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 Panel Observation Conditional Reporting

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

**Table 2.6.1: Conditional Reporting**

| Observation Display Name *(from Table 2.5.1 and/or 2.5.2)* | Result Display Name *(from Table 2.4.1)* | Reporting Condition |
|---|---|---|
| PCR2 Control Tm Value A<br>PCR2 Control Tm Value B<br>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.<br>*e.g., if two Tm values are found for the PCR2 control, only two of the three observations will be sent* |
| | | Otherwise, the observation is **not** included in the electronic report. |
| RNA Process Control Tm Value A<br>RNA Process Control Tm Value B<br>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.<br>*e.g., if two Tm values are found for the PCR2 control, only two of the three observations will be sent* |
| | | Otherwise, the observation is **not** included in the electronic report. |

## 2.7. SPOTFIRE Respiratory Panel Warnings and Notes

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

# 3. Technical Support Contact Information

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

**Technical Support**
Email: biofiresupport@biomerieux.com
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