August 14, 2025

BioFire Diagnostics, LLC
Karli Plenert
Sr. Director, Regulatory Affairs
515 Colorow Drive
Salt Lake City, Utah 84108

Re: K243544
Trade/Device Name: BIOFIRE SPOTFIRE Respiratory/Sore Throat Panel Mini
Regulation Number: 21 CFR 866.3981
Regulation Name: Device To Detect And Identify Nucleic Acid Targets In Respiratory Specimens From Microbial Agents That Cause The SARS-CoV-2 Respiratory Infection And Other Microbial Agents When In A Multi-Target Test
Regulatory Class: Class II
Product Code: QOF
Dated: November 14, 2024
Received: November 15, 2024

Dear Karli Plenert:

We have reviewed your section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (the Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801 and Part 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-

assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

ANNA M. MIELECH -S

Anna Mielech, PhD.
Deputy Branch Chief (Acting)
Viral Respiratory and HPV Branch
Division of Microbiology Devices
OHT7: Office of In Vitro Diagnostics
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K243544

Device Name
BIOFIRE SPOTFIRE Respiratory/Sore Throat (R/ST) Panel Mini

Indications for Use *(Describe)*
The BIOFIRE SPOTFIRE Respiratory/Sore Throat (R/ST) Panel Mini is an automated multiplexed polymerase chain reaction (PCR) test intended for use with the BIOFIRE SPOTFIRE System for the simultaneous, qualitative detection and identification of multiple respiratory viral and bacterial nucleic acids in nasopharyngeal swab (NPS) or anterior nasal swab (ANS) specimens obtained from individuals with signs and symptoms of respiratory tract infection, including COVID-19; (Respiratory menu) or in throat swab (TS) specimens from individuals with signs and symptoms of pharyngitis; (Sore Throat menu).

The following analytes are identified and differentiated using the BIOFIRE SPOTFIRE R/ST Panel Mini:

Respiratory Menu
Viruses
Coronavirus SARS-CoV-2
Human rhinovirus
Influenza A virus
Influenza B virus
Respiratory syncytial virus

Sore Throat Menu
Viruses
Human rhinovirus
Influenza A virus
Influenza B virus
Respiratory syncytial virus

Bacteria
Streptococcus pyogenes (group A Strep)

Nucleic acids from the viral and bacterial organisms identified by this test are generally detectable in NPS/ANS/TS specimens during the acute phase of infection. The detection and identification of specific viral and bacterial nucleic acids from individuals exhibiting signs and symptoms of respiratory infection and/or pharyngitis is indicative of the presence of the identified microorganism and aids in diagnosis if used in conjunction with other clinical and epidemiological information, and laboratory findings. The results of this test should not be used as the sole basis for diagnosis, treatment, or other patient management decisions.

Negative results in the setting of a respiratory illness and/or pharyngitis may be due to infection with pathogens that are not detected by this test, or a respiratory tract infection that may not be detected by an NPS, ANS, or TS specimen. Positive results do not rule out co-infection with other organisms. The agent(s) detected by the BIOFIRE SPOTFIRE R/ST Panel Mini may not be the definite cause of disease.

Additional laboratory testing (e.g., bacterial and viral culture, immunofluorescence, and radiography) may be necessary when evaluating a patient with possible respiratory tract infection and/or pharyngitis.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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BIOFIRE® SPOTFIRE® Respiratory/Sore Throat (R/ST) Panel Mini

510(k) Summary
BioFire Diagnostics, LLC

Introduction:

The purpose of this 510(k) submission is to obtain clearance for the BIOFIRE® SPOTFIRE® Respiratory/Sore Throat (R/ST) Panel Mini (SPOTFIRE R/ST Panel Mini) with the addition of anterior nasal swabs (ANS) as a sample type for the Respiratory Menu. The SPOTFIRE R/ST Panel Mini is compatible with the BIOFIRE® SPOTFIRE® System, an automated, polymerase chain reaction (PCR)-based in vitro diagnostic system for infectious disease testing.

According to the requirements of 21 CFR 807.92, the information included with this submission provides sufficient detail to understand the basis for a determination of substantial equivalence.

Submitted by:

BioFire Diagnostics, LLC (bioMérieux)
515 Colorow Drive
Salt Lake City, UT 84108

Contact: Karli Plenert, MBA
Telephone: 385-414-4985
Email: Karli.Plenert@biomerieux.com

Date submitted: August 08, 2025

Device Name and Classification:

Trade name: BIOFIRE® SPOTFIRE® Respiratory/Sore Throat (R/ST) Panel Mini

Regulation Number for Device Classification: 21 CFR 866.3981

Classification Name: Multi-Target Respiratory Specimen Nucleic Acid Test Including SARS-CoV-2 And Other Microbial Agents

Product Code: QOF

Predicate Device:
K241194 – BIOFIRE® SPOTFIRE® Respiratory/Sore Throat (R/ST) Panel Mini

Intended Use:

The BIOFIRE® SPOTFIRE® Respiratory/Sore Throat (R/ST) Panel Mini is an automated, multiplexed, polymerase chain reaction (PCR) test intended for use with the BIOFIRE® SPOTFIRE® System for the simultaneous, qualitative detection and identification of multiple respiratory viral and bacterial nucleic acids in nasopharyngeal swab (NPS) and anterior nasal swab (ANS) specimens obtained from **individuals with signs and symptoms of respiratory tract infection**, **including COVID-19;** (**Respiratory menu**) or in throat swab (TS) specimens from **individuals with signs and symptoms of pharyngitis;** (**Sore Throat menu**).

The following analytes are identified and differentiated using the BIOFIRE SPOTFIRE R/ST Panel Mini:

Table 1. SPOTFIRE R/ST Panel Mini Analytes

Respiratory Menu	Sore Throat Menu
Viruses	Viruses
Coronavirus SARS-CoV-2	Human rhinovirus
Human rhinovirus	Influenza A virus
Influenza A virus	Influenza B virus
Influenza B virus	Respiratory syncytial virus
Respiratory syncytial virus	Bacteria
	Streptococcus pyogenes (group A Strep)

Nucleic acids from the viral and bacterial organisms identified by this test are generally detectable in NPS/ANS/TS specimens during the acute phase of infection. The detection and identification of specific viral and bacterial nucleic acids from individuals exhibiting signs and symptoms of respiratory infection and/or pharyngitis is indicative of the presence of the identified microorganism and aids in diagnosis if used in conjunction with other clinical and epidemiological information, and laboratory findings. The results of this test should not be used as the sole basis for diagnosis, treatment, or other patient management decisions.

Negative results in the setting of a respiratory illness and/or pharyngitis may be due to infection with pathogens that are not detected by this test, or a respiratory tract infection that may not be detected by an NPS, ANS, or TS specimen. Positive results do not rule out co-infection with other organisms. The agent(s) detected by the BIOFIRE SPOTFIRE R/ST Panel Mini may not be the definite cause of disease.

Additional laboratory testing (e.g., bacterial and viral culture, immunofluorescence, and radiography) may be necessary when evaluating a patient with possible respiratory tract infection and/or pharyngitis.

Device Description:

The BIOFIRE SPOTFIRE R/ST Panel Mini (SPOTFIRE R/ST Panel Mini) simultaneously identifies 5 different respiratory viral pathogens in nasopharyngeal swabs (NPS) or anterior nasal swabs (ANS), or 5 different viral and bacterial pharyngitis pathogens in throat swabs (TS) from individuals with signs and symptoms of respiratory tract infections or pharyngitis, respectively, (see Table 1). The SPOTFIRE R/ST Panel Mini is compatible with the BIOFIRE® SPOTFIRE® System, a polymerase chain reaction (PCR)-based in vitro diagnostic system for infectious disease testing. The BIOFIRE SPOTFIRE System Software executes the SPOTFIRE R/ST Panel Mini test and interprets and reports the test results. The SPOTFIRE R/ST Panel Mini was designed to be used in CLIA-waived environments.

A test is initiated by loading Hydration Solution into the hydration solution injection port of the SPOTFIRE R/ST Panel Mini pouch and NPS, ANS, or TS specimen, mixed with the provided Sample Buffer, into the other sample injection port of the SPOTFIRE R/ST Panel Mini pouch and placing it in the SPOTFIRE System. The pouch contains all the reagents required for specimen testing and analysis in a freeze-dried format; the addition of Hydration Solution and Sample/Buffer Mix rehydrates the reagents. After the pouch is prepared, the SPOTFIRE System Software guides the user through the steps of placing the pouch into the instrument, scanning the pouch barcode, entering the sample identification, and initiating the run.

Nucleic acid extraction occurs within the SPOTFIRE R/ST Panel Mini pouch using mechanical and chemical lysis followed by purification using standard magnetic bead technology. After extracting and purifying nucleic acids from the unprocessed sample, the SPOTFIRE System performs a nested multiplex PCR that is executed in two stages. During the first stage, the SPOTFIRE System performs a single, large volume, highly multiplexed reverse transcription PCR (rt-PCR) reaction. The products from first stage PCR are then diluted and combined with a fresh, primer-free master mix and a fluorescent double-stranded DNA binding dye (LC Green® *Plus*, BioFire Diagnostics). The solution is then distributed to each well of the array. Array wells contain sets of primers designed specifically to amplify sequences internal to the PCR products generated during the first stage PCR reaction. The 2nd stage PCR, or nested PCR, is performed in singleplex fashion in each well of the array. At the conclusion of the 2nd stage PCR, the array is interrogated by melt curve analysis for the detection of signature amplicons denoting the presence of specific targets. A digital camera placed in front of the 2nd stage PCR captures fluorescent images of the PCR reactions and software interprets the data.

The SPOTFIRE System Software automatically interprets the results of each DNA melt curve analysis and combines the data with the results of the internal pouch controls to provide a test result for each organism on the SPOTFIRE R/ST Panel Mini.

Substantial Equivalence:

The BIOFIRE SPOTFIRE R/ST Panel Mini with ANS sample type for use with the Respiratory menu is substantially equivalent to the BIOFIRE SPOTFIRE R/ST Panel Mini (K241194), which was cleared via the Special 510(k) pathway on May 30, 2024, and determined to be a Class II device under the classification code 21 CFR 866.3981.

A comparison of the BIOFIRE SPOTFIRE R/ST Panel Mini to the BIOFIRE SPOTFIRE R/ST Panel Mini with ANS sample type is provided in Table 1.

Table 1 Similarities and differences between the BIOFIRE SPOTFIRE R/ST Panel Mini and the BIOFIRE SPOTFIRE R/ST Panel Mini with ANS sample type

Element	BIOFIRE SPOTFIRE R/ST Panel Mini (K241194)	BIOFIRE SPOTFIRE R/ST Panel Mini (this submission)
Intended Use	The BIOFIRE® SPOTFIRE® Respiratory/Sore Throat (R/ST) Panel Mini is a multiplexed polymerase chain reaction (PCR) test intended for use with the BIOFIRE® SPOTFIRE® System for the simultaneous, qualitative detection and identification of multiple respiratory viral and bacterial nucleic acids in nasopharyngeal swab (NPS) specimens obtained from **individuals with signs and symptoms of respiratory tract infection**, **including COVID-19**; (**Respiratory menu**) or in throat swab (TS) specimens from **individuals with signs and symptoms of pharyngitis** (**Sore Throat menu**). The following analytes are identified and differentiated using the SPOTFIRE R/ST Panel Mini: **Respiratory Menu** Viruses Coronavirus SARS-CoV-2 Human rhinovirus Influenza A virus Influenza B virus Respiratory syncytial virus **Sore Throat Menu** Viruses Human rhinovirus Influenza A virus Influenza B virus Respiratory syncytial virus Bacteria *Streptococcus pyogenes* (group A Strep)	The BIOFIRE® SPOTFIRE® Respiratory/Sore Throat (R/ST) Panel Mini is an automated, multiplexed, polymerase chain reaction (PCR) test intended for use with the BIOFIRE® SPOTFIRE® System for the simultaneous, qualitative detection and identification of multiple respiratory viral and bacterial nucleic acids in nasopharyngeal swab (NPS) and anterior nasal swab (ANS) specimens obtained from **individuals with signs and symptoms of respiratory tract infection**, **including COVID-19** (**Respiratory menu**); or in throat swab (TS) specimens from **individuals with signs and symptoms of pharyngitis** (**Sore Throat menu**). The following analytes are identified and differentiated using the SPOTFIRE R/ST Panel Mini: **Respiratory Menu** Viruses Coronavirus SARS-CoV-2 Human rhinovirus Influenza A virus Influenza B virus Respiratory syncytial virus **Sore Throat Menu** Viruses Human rhinovirus Influenza A virus Influenza B virus Respiratory syncytial virus Bacteria *Streptococcus pyogenes* (group A Strep)

Specimen Types	Nasopharyngeal swab in transport media or Throat swab in transport media	Nasopharyngeal swab in transport media, Anterior nasal swab in transport media, or Throat swab in transport media
Organisms detected	**Viruses** Coronavirus SARS-CoV-2 (Respiratory Menu only) Human rhinovirus Influenza A virus Influenza B virus Respiratory syncytial virus **Bacteria** *Streptococcus pyogenes* (group A Strep) (Sore Throat Menu only)	Same
Analytes	DNA/RNA	Same
Technological Principles	Highly multiplexed nested nucleic acid amplification test with melt analysis	Same
Instrumentation	BIOFIRE SPOTFIRE System	Same
Time to result	About 15 minutes	Same
Reagent Storage	Room Temperature	Same
Test Interpretation	Automated test interpretation and reporting. User cannot access raw data.	Same
Panel Software Functions	Defines panel-specific parameters, instrument protocols and report requirements.	Same
	Analyzes processed image data (fluorescence and temperature data) and provides test results.	Same
	Analyzes processed image data (fluorescence and temperature data) and provides test results.	Same

Summary of Performance Data:

The performance data for the BIOFIRE SPOTFIRE R/ST Panel Mini is summarized in the *BIOFIRE SPOTFIRE Respiratory/Sore Throat Panel Mini Instructions for Use*. A summary of the SPOTFIRE R/ST Panel Mini performance data for ANS sample type and additional analytical specificity and interference is provided below.

Clinical Performance

The clinical performance of the SPOTFIRE R/ST Panel Mini when testing ANS specimens was established during a prospective multi-center study that was further supplemented with archived specimens due to low prevalence of influenza B in prospective clinical study. Five geographically distinct urgent care or emergency department study sites located in the US and representative of the intended use setting participated in the prospective clinical study from March 2024 to February 2025. All SPOTFIRE R/ST Panel Mini testing was performed according to the manufacturer's instructions by operators with training and educational backgrounds representative of those in the CLIA-waived setting.

A total of 820 ANS specimens were initially enrolled in the prospective clinical study from consented volunteers from subjects of all ages; 23 of these were excluded from all analyses. Eleven (11) specimens were excluded because no valid SPOTFIRE R/ST Panel Mini test for the ANS specimen was obtained, eight were excluded because no valid comparator test was obtained, and four additional specimens were excluded due to those specimens having been determined to not meet the inclusion criteria after initial enrollment. The final data set consisted of 797 specimens. Additionally, six of the 797 specimens were excluded from the evaluation of influenza A virus due to initial 'Uncertain' results that were not appropriately retested by operators at study sites (N=4) or initial inconclusive comparator results that were unable to be retested due to insufficient volume (N=2).

Table 2 provides a summary of demographic information for the specimens included in the study.

Table 2. Demographic Summary for the SPOTFIRE R/ST Panel Mini ANS Sample Type Addition Prospective Clinical Evaluation

Category		Prospective
Sex	Male	358 (44.9%)
	Female	439 (55.1%)
Age	≤5 years	240 (30.1%)
	6-18 years	213 (26.7%)
	19-40 years	178 (22.3%)
	41-60 years	116 (14.6%)
	61+ years	50 (6.3%)
Total		**797**

For each analyte, the performance of the SPOTFIRE R/ST Panel Mini when testing ANS specimens was evaluated by comparing the test results with those from a commercially available FDA-cleared multiplexed respiratory pathogen panel.

The performance for the ANS sample type addition prospective study is summarized in Table 3. Positive percent agreement (PPA) for each analyte was calculated as 100% × (TP / (TP + FN)). True positive (TP) indicates that both the SPOTFIRE R/ST Panel Mini and the comparator method had a positive result for the specific analyte, and false negative (FN) indicates that the SPOTFIRE R/ST Panel Mini was negative while the comparator result was positive. Negative percent agreement (NPA) was calculated as 100% × (TN / TN + FP)). True negative (TN) indicates that both the SPOTFIRE R/ST Panel Mini and the comparator method had negative results, and false positive (FP) indicates that the SPOTFIRE R/ST Panel Mini was positive while the comparator method was negative. The exact binomial two-sided 95% confidence interval (95%CI) was calculated. Investigations of discrepant results are summarized in the footnotes.

Table 3. SPOTFIRE R/ST Panel Mini ANS Sample Type Addition Prospective Clinical Performance Summary for ANS Specimens

SPOTFIRE R/ST Panel Mini R Menu Analyte	Positive Percent Agreement			Negative Percent Agreement		
	TP/(TP + FN)	%	95%CI	TN/(TN + FP)	%	95%CI
Coronavirus SARS-CoV-2[a]	50/52	96.2	87.0-98.9%	742/745	99.6	98.8-99.9%
Human rhinovirus[b]	222/232	95.7	92.2-97.6%	537/565	95.0	92.9-96.5%
Influenza A virus[c]	50/53	94.3	84.6-98.1%	738/738	100	99.5-100%
Influenza B virus	13/13	100	77.2-100%	784/784	100	99.5-100%
Respiratory syncytial virus[d]	38/40	95.0	83.5-98.6%	756/757	99.9	99.3-100%

[a] SARS-CoV-2 was detected in 1/3 FP specimens when tested with additional molecular methods.
[b] Human rhinovirus was detected in 1/28 FP specimens using an additional molecular method.
[c] Influenza A virus was detected in all three FN specimens using an additional molecular method.
[d] Respiratory syncytial virus was detected in the single FP specimen using an additional molecular method.

The overall success rate for initial specimen tests was 97.0% (782/806). Nine tests (9/806; 1.1%) did not complete on the initial test attempt, resulting in an instrument success rate of 98.9% (797/806) for initial specimen tests. Of the 797 tests that successfully produced a completed run on the initial test, 782 had valid internal process controls. This represents a 98.1% (782/797) success rate for internal process controls in completed runs in the initial specimen tests. While 782 specimens were successful on the initial test, successful retesting of 23 specimens and eight additional specimen exclusions unrelated to the system performance brings the total number of valid specimens analyzed to 797.

The archived specimen testing performance is summarized in Table 4.

Table 4. SPOTFIRE R/ST Panel Mini R/ST Respiratory Menu Performance Summary for All Confirmed, Valid Archived ANS Specimens

Analyte	PPA			NPA		
	TP/(TP + FN)	%	95% CI	TN/(TN + FP)	%	95% CI
Influenza B virus	35/35	100	90.1-100%	206/206	100	98.2-100%

The prospective data combined with the archived data demonstrate acceptable performance of the SPOTFIRE R/ST Panel Mini for use with ANS specimens.

Analytical Performance

To supplement the analytical specificity and interference testing performed for the initial release of the BIOFIRE SPOTFIRE R/ST Panel Mini, three additional off-panel organisms were tested for specificity (Table 5) and 13 additional off-panel organisms were tested for interference (Table 6).

Table 5. Summary of Results for Additionally Tested Off-Panel Organisms for Evaluation of Analytical Specificity of the SPOTFIRE R/ST Panel Mini

Organism	Isolate ID	Concentration Tested	Observed Cross-Reactivity
Bacteria			
Eikenella corrodens	ATCC BAA-1152	8.2E+09 cells/mL	None
Nocardia brasiliensis	ATCC 19019	1.2E+09 CFU/mL	None
Fungi			
Pneumocystis jirovecii	ATCC PRA-159	2.0E+07 nuclei/mL	None

Table 6. Additional Substances Tested on the SPOTFIRE R/ST Panel Mini - No Interference Observed

Substance Tested	Concentration Tested
Competing Microorganisms	
Off-Panel	
Epstein-Barr virus (EBV)	5.9E+06 copies/mL
Eikenella corrodens	8.2E+08 Cells/mL
Lactobacillus rhamnosus	7.9E+08 Cells/mL
Legionella pneumophila	7.0E+08 Cells/mL
Neisseria meningitidis	7.4E+08 Cells/mL
Nocardia brasiliensis	1.2E+08 CFU/mL
Porphyromonas gingivalis	5.0E+07 Cells/mL
Prevotella oralis	6.2E+07 Cells/mL
Pseudomonas aeruginosa	8.3E+08 Cells/mL
Staphylococcus epidermidis	8.0E+08 Cells/mL
Streptococcus mitis	3.2E+08 Cells/mL
Streptococcus mutans	2.3E+08 Cells/mL
Streptococcus salivarius	6.6E+08 Cells/mL

Conclusion:

The fundamental scientific technology, performance, and risk of the SPOTFIRE R/ST Panel Mini remain unchanged from the predicate device. There is no change to the product itself, except for the addition of ANS as a new sample type for the Respiratory Menu, for which the performance has been shown to be substantially equivalent to the predicate device.