September 30, 2025

Centers for Disease Control and Prevention
Andita Clarke
Quality Assurance Specialist
1600 Clifton Road NE, MS: H24-2
Atlanta, Georgia 30329

Re: K252072
Trade/Device Name: *Francisella tularensis* Real-time PCR Assay
Regulation Number: 21 CFR 866.4000
Regulation Name: Device To Detect And Identify Biothreat Microbial Agents In Human Clinical Specimens
Regulatory Class: Class II
Product Code: SGA
Dated: July 1, 2025
Received: July 1, 2025

Dear Andita Clarke:

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.

FDA's substantial equivalence determination also included the review and clearance of your Predetermined Change Control Plan (PCCP). Under section 515C(b)(1) of the Act, a new premarket notification is not required for a change to a device cleared under section 510(k) of the Act, if such change is consistent with an established PCCP granted pursuant to section 515C(b)(2) of the Act. Under 21 CFR 807.81(a)(3), a new premarket notification is required if there is a major change or modification in the intended use of a device, or if there is a change or modification in a device that could significantly affect the safety or effectiveness of the device, e.g., a significant change or modification in design, material, chemical composition, energy source, or manufacturing process. Accordingly, if deviations from the established PCCP result in a major change or modification in the intended use of the device, or result in a change or modification in the device that could significantly affect the safety or effectiveness of the device, then a new premarket notification would be required consistent with section 515C(b)(1) of the Act and 21 CFR 807.81(a)(3). Failure to submit such a premarket submission would constitute adulteration and misbranding under sections 501(f)(1)(B) and 502(o) of the Act, respectively.

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,

Bryan M. Grabias -S

Digitally signed by Bryan M. Grabias -S
Date: 2025.09.30 10:43:34 -04'00'

Bryan Grabias, Ph. D.
Acting Branch Chief
Bacterial Respiratory and Medical Countermeasures Branch
Division of Microbiology Devices
OHT7: Office of In Vitro Diagnostics
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

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

510(k) Number *(if known)*
K252072

Device Name
Francisella tularensis Real-time PCR assay

Indications for Use *(Describe)*
The Francisella tularensis Real-time PCR Assay is an in vitro diagnostic test for the qualitative detection of chromosomal DNA sequences from Francisella tularensis. The assay can be used to test whole blood EDTA, pleural fluid, and bacterial culture isolates grown on agar from individuals suspected of having tularemia.

Results generated from direct specimen testing are presumptive for the identification of Francisella tularensis. Results generated from culture isolate testing are used as part of the LRN Francisella tularensis Testing Algorithm. The diagnosis of Francisella tularensis infection must be made based on history, signs, symptoms, exposure likelihood, and other laboratory evidence, in addition to the identification of Francisella tularensis from culture isolates or from clinical specimens.

Negative results do not preclude infection with the biothreat microbial agents targeted by the device and should not be used as the sole basis for diagnosis, treatment, or other patient management decisions.

Use is limited to Centers for Disease Control and Prevention (CDC) designated laboratories.

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.

510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR 807.92.

Assigned 510(k) number:

Submitted by:	Centers for Disease Control and Prevention 1600 Clifton Road NE Atlanta, GA 30329
Contact Person:	Jasmine Chaitram, MPH Acting Deputy Director for Readiness and Response Office of Laboratory Systems and Response Centers for Disease Control and Prevention (Registration number: 1050190) 1600 Clifton Road, NE, MS H24-12 Atlanta, GA 30329 (404) 498-1635 (office) JChaitram@cdc.gov
Date prepared:	July 1, 2025
Device trade name:	*Francisella tularensis* Real-time PCR Assay
Classification name and regulation: (if applicable)	Class II, 21 CFR 866.4000 Multiplex Nucleic Acid Detection System For Biothreat Agents
Predicate device(s):	The Biofire FilmArray® NGDS Warrior Panel (K170883)

Device Description

The *Francisella tularensis* Real-time PCR Assay is composed of oligonucleotide primers and dual-labeled hydrolysis probes (Taqman®) for use in real-time PCR reactions. This assay is intended for the *in vitro* detection of *Francisella tularensis* in individuals suspected of having tularemia. Extracted DNA samples are tested using the *Francisella tularensis* Real-time PCR Assay along with an extraction control primer and probe set to demonstrate adequate DNA extraction and isolation, specimen integrity, proper function of common reagents and equipment, and the absence of inhibitory substances.

Assay Principle

The *Francisella tularensis* Real-time PCR Assay panel is based on real-time PCR technology used in many molecular diagnostic assays to date. The *Francisella tularensis* Real-time PCR Assay consists of Ft Pan1 and Ft Pan2 primer and probe sets designed for universal detection of *Francisella tularensis* bacteria. The assay also includes an additional control primer and probe set, RNase P (RP), which detects human RNase P to indicate adequate isolation of nucleic acid resulting from the extraction of the clinical specimen. A positive result in the RP assay indicates adequate specimen was present, ensures that common reagents and equipment are performing as expected and demonstrates the absence of inhibitory substances. A Human Specimen Control (HSC) is a noninfectious cultured human cell material that demonstrates successful recovery of DNA as well as extraction reagent integrity. The Ft Real-time PCR Positive DNA Control consists of a plasmid containing regions that are positive for both Ft Pan1 and Ft Pan2. The plasmid also contains a viral hemorrhagic septicemia virus (VHSV) gene for use as a contamination control. VHSV is a rhabdovirus that infects fish and is not pathogenic for humans and other animals.

Intended Use

The *Francisella tularensis* Real-time PCR Assay is an *in vitro* diagnostic test for the qualitative detection of chromosomal DNA sequences from *Francisella tularensis*. The assay can be used to test whole blood EDTA, pleural fluid, and bacterial culture isolates grown on agar from individuals suspected of having tularemia.

Results generated from direct specimen testing are presumptive for the identification of *Francisella tularensis.* Results generated from culture isolate testing are used as part of the LRN Francisella tularensis Testing Algorithm. The diagnosis of *Francisella tularensis* infection must be made based on history, signs, symptoms, exposure likelihood, and other laboratory evidence, in addition to the identification of *Francisella tularensis* from culture isolates or from clinical specimens.

Negative results do not preclude infection with the biothreat microbial agents targeted by the device and should not be used as the sole basis for diagnosis, treatment, or other patient management decisions.

Use is limited to Centers for Disease Control and Prevention (CDC) designated laboratories.

Establishment of Performance Characteristics

Inquiries regarding performance characteristics for the *Francisella tularensis* Real-time PCR Assay should be directed to the Centers for Disease Control and Prevention.

Analytical Limit of Detection (LoD)

The limit of detection for the *Francisella tularensis* Real-time PCR Assay was determined through an analytical sensitivity study.

Analytical Sensitivity and Specificity

Inquiries regarding performance characteristics for the *Francisella tularensis* Real-time PCR Assay should be directed to the Centers for Disease Control and Prevention.

Clinical Performance

Inquiries regarding clinical performance characteristics for the *Francisella tularensis* Real-time PCR Assay should be directed to the Centers for Disease Control and Prevention.

Predetermined Change Control Plan

A Predetermined Change Control Plan (PCCP) for the *Francisella tularensis* Real-time PCR Assay is included with the FDA 510(k) Premarket Notification. The PCCP defines the types of modifications that can be evaluated, reviewed, and implemented without a requirement to submit the change to FDA for review prior to implementation. Under the authorized PCCP, anticipated modifications to the *Francisella tularensis* Real-time PCR Assay include addition of Real-time PCR instruments, extraction methods and instruments, and PCR reaction master mixes. Modifications will be evaluated and implemented with defined modification protocols and acceptance criteria under the authorized PCCP and CDC's quality management system. Implementation will include notification to end users of the specific modification and updates to procedural and performance information related to the CDC Francisella tularensis Real-time PCR Assay.

Substantial Equivalence Comparison

Both the *Francisella tularensis* Real-time PCR Assay and the FilmArray® NGDS Warrior Panel require extraction of nucleic acid from the specimen followed by nucleic acid amplification of specific *F. tularensis* target sequences. The *Francisella tularensis* Real-time PCR Assay includes a manual DNA extraction step before nucleic acid amplification and detection of probe degradation by fluorescence. The FilmArray® NGDS Warrior Panel pouch is a closed system that includes sample extraction, nucleic acid amplification, and detection using endpoint melting curve data.

	Device ***Francisella tularensis* Real-time PCR Assay**	*Predicate* **The FilmArray® NGDS Warrior Panel**
Intended Use	The *Francisella tularensis* Real-time PCR Assay is an *in vitro* diagnostic test for the qualitative detection of chromosomal DNA sequences from *Francisella tularensis*. The assay can be used to test whole blood EDTA, pleural fluid, and bacterial culture isolates grown on agar from individuals suspected of having tularemia. Results generated from direct specimen testing are presumptive for the identification of *Francisella tularensis.* Results generated from culture isolate testing are used as part of the LRN Francisella tularensis Testing Algorithm. The diagnosis of *Francisella tularensis* infection must be made based on history, signs, symptoms, exposure likelihood, and other laboratory evidence, in addition to the identification of *Francisella tularensis* from cultures isolates or from clinical specimens. Negative results do not preclude infection with the biothreat microbial agents targeted by the device	The FilmArray® NGDS Warrior Panel is a qualitative, multiplexed, nucleic acid-based in vitro diagnostic test intended for use with the FilmArray® 2.0 system. The FilmArray® NGDS Warrior Panel detects and identifies Bacillus anthracis, Yersinia pestis, Francisella tularensis, Coxiella burnetii, Ebola virus, and Marburg virus nucleic acids directly from human whole blood (EDTA). The FilmArray® NGDS Warrior Panel is also intended to be used to test for Bacillus anthracis or Yersinia pestis nucleic acids in blood cultures that are determined to be positive either by an automated system, by turbidity, or by daily Gram stain even without turbidity, and is indicated to be performed with concomitant Gram stain performed on positive blood culture specimens as per normal laboratory procedure. In addition, the FilmArray® NGDS Warrior Panel may also be used to detect and identify Yersinia pestis and Francisella tularensis nucleic acids directly from sputum specimens. The FilmArray® NGDS Warrior Panel is intended to test individuals with signs and symptoms of infection from biothreat agents and/or individuals who are at risk for exposure or may have been exposed to these agents. The FilmArray® NGDS Warrior Panel is indicated as an aid in the diagnosis of anthrax, plague, tularemia, Q fever, and the

	Device ***Francisella tularensis* Real-time PCR Assay**	*Predicate* **The FilmArray® NGDS Warrior Panel**
	and should not be used as the sole basis for diagnosis, treatment, or other patient management decisions. Use is limited to Centers for Disease Control and Prevention (CDC) designated laboratories.	hemorrhagic fevers caused by Ebola and Marburg viruses, in response to a suspected or confirmed bioterrorism event or outbreaks. It is for diagnostic use in conjunction with other clinical, epidemiologic, and laboratory data, in accordance with the guidelines provided by the appropriate Department of Defense and public health authorities. Results are for the presumptive identification of Bacillus anthracis, Yersinia pestis, Francisella tularensis, Coxiella burnetii, Ebola virus, and Marburg virus. The definitive identification of Bacillus anthracis, Yersinia pestis, Francisella tularensis, Coxiella burnetii, Ebola virus, and Marburg virus requires additional testing and confirmation procedures in consultation with the appropriate Department of Defense and public health authorities for whom reports may be necessary. Negative results do not preclude infection with these biothreat agents and should not be used as the sole basis for diagnosis, treatment, or other patient management decisions. The FilmArray® NGDS Warrior Panel is solely for use by United States Department of Defense laboratories, and laboratories designated by the Department of Defense.
Principle of Operation	Nucleic acid amplification and fluorescent probe detection	Specimen extraction, reverse transcription, nucleic acid amplification and endpoint melting curve analysis

Targets	• *Francisella tularensis* subspecies:
	  ○ *F.t. tularensis*,
	  ○ *F.t. holarctica*,
	  ○ *F.t. mediasiatica*
		• *Bacillus anthracis* (with virulence plasmids pXO1 & pXO2)
		• *Yersinia pestis*
		• *Francisella tularensis*
		• *Coxiella burnetii*
		• Ebola Virus
		• Marburg

Sample Types	• Whole Blood (EDTA) • Pleural Fluid • Culture isolates	• Whole blood (EDTA) • Sputum
Instrumentation	• Applied Biosystems™ 7500 Fast Dx Real-Time PCR Instrument • QuantStudio™ Dx Real-Time PCR Instrument	• FilmArray® 2.0 system
Software	• AB 7500 Fast Dx Real-Time PCR Instrument SDS software v1.4.1 • QuantStudio Dx (QSDx) Real-time PCR Instrument Emerging Pathogens Edition software v1.0.1	• FilmArray® software
Enzyme	• Quanta PerfeCTa MultiPlex qPCR SuperMix, Low ROX	• Not specified in the FilmArray NGDS Warrior Panel instructions for use

Conclusion

The results of analytical and clinical performance studies demonstrated that the *Francisella tularensis* Real-time PCR Assay is substantially equivalent to the predicate device.