K131936

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10 510(k) Summary

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BioFire Diagnostics, Inc.

Modification of the JBAIDS Tularemia Detection Kit for use with the IT *1-2-3*™ Platinum Path Sample Purification Kit Accessory

Introduction: According to the requirements of 21 CFR 807.92, the following information provides sufficient detail to understand the basis for a determination of substantial equivalence.

Submitted by:

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Contact: Cynthia Phillips, ext. 370

Date Submitted: June 25, 2013

Device Name and Classification:

Trade Name: JBAIDS Tularemia Detection Kit

Regulation Number: 21 CFR 866.3280

Classification Name: Reagent Kit: *F. tularensis*, Class II

Product Code: OEH

Predicate Device:

JBAIDS Tularemia Detection Kit (K072547)

Intended Use:

The Joint Biological Agent Identification and Diagnostic System (JBAIDS) Tularemia Detection Kit is a real-time polymerase chain reaction (PCR) test kit intended for the qualitative *in vitro* diagnostic (IVD) detection of target DNA sequences of *Francisella tularensis*. The system can be used to test human whole blood collected in sodium citrate

or sputum collected aseptically from individuals greater than 18 years of age suspected of having tularemia. In addition, positive blood cultures and colonies may be tested. This assay is intended to aid in the diagnosis of individual presenting with signs and symptoms of pneumonic or typhoidal tularemia. It is not intended to aid in the diagnosis of glandular, ulceroglandular, oculoglandular, or oropharyngeal tularemia.

The JBAIDS Tularemia Detection Kit is run on the JBAIDS instrument using the Diagnostic Wizard. Results are for the presumptive identification of *F. tularensis* in conjunction with culture and other laboratory tests. The definitive identification of *F. tularensis* from colony growth, liquid blood culture growth, blood specimens, or sputum specimens requires additional testing and confirmation procedures in consultation with public health or other authorities for whom reports are required.

The diagnosis of tularemia must be made based on history, signs, symptoms, exposure likelihood, and other laboratory evidence in addition to the identification of the target either from colonies, blood culture whole blood or sputum specimens.

The JBAIDS Tularemia Detection Kit is intended for use by trained clinical laboratory personnel who have received specific training on the use of the JBAIDS Tularemia Detection Kit. The level of *F. tularensis* that would be present in blood or sputum from individuals with early systemic or pneumonic infection is unknown. Due to the difficulty in obtaining clinical specimens, this assay was not evaluated with blood or sputum from individuals presenting with signs and symptoms of tularemia who have subsequently developed pneumonic or typhoidal tularemia pneumonic or typhoidal tularemia.

Device Description:

The Joint Biological Agent Identification and Diagnostic System (JBAIDS) Tularemia Detection System is a fully integrated IVD system composed of the portable JBAIDS instrument, laptop computer and software and the JBAIDS Tularemia Detection Kit with one freeze-dried PCR assay for detection of *Francisella tularensis* DNA. The system has been validated using four different sample preparation kits for isolating DNA from whole blood (IT *1-2-3*™ Platinum Path and QFLOW^{dna} Sample Purification Kits), sputum (IT *1-2-3*™ Platinum Path and IT *1-2-3*™ VIBE Sample Purification Kits), positive blood cultures (IT *1-2-3*™ SWIPE Sample Purification Kit), and plate cultures (IT *1-2-3*™ Platinum Path and IT *1-2-3*™ SWIPE Sample Purification Kits). Use of the JBAIDS DNA Extraction Control Kit is also recommended.

Prior to testing, specimens are processed using BioFire Diagnostic's IT *1-2-3* Sample Purification Kits. The resulting purified sample is added to Unknown and Inhibition Control vials, along with reconstitution buffer. Positive Control and Negative Control vials are prepared using reconstitution buffer and water. When *F. tularensis* DNA is present, a fragment of *F. tularensis* DNA is amplified. The amplicon is detected by fluorescence using a specific hydrolysis probe. Each probe is labeled on one end with a fluorescent reporter moiety (6-carboxyfluorescein (6-FAM)) and elsewhere with a quencher moiety (carboxy tetramethylrhodamine (TAMRA)). When the probe is intact, the quencher absorbs the light emitted by the reporter moiety. During PCR, the probe hybridizes to the target sequence before the exonuclease activity of Taq polymerase

hydrolyzes the probe, separating the fluorophore from the quencher and permitting detection of the fluorescent signal generated by the reporter. The fluorescent signal increases as additional templates are amplified and more probes are hydrolyzed.

JBAIDS Software analyzes the fluorescence amplification curves and reports results as positive, negative, uncertain or inhibited. A failure of the Positive or Negative Control will result in the entire run being called invalid. Retesting is required to resolve uncertain, invalid or inhibited results.

Substantial Equivalence:

The JBAIDS Tularemia Detection Kit is substantially equivalent to the previously cleared JBAIDS Tularemia Detection Kit. The following tables compare the modified JBAIDS Tularemia Detection Kit to the previously cleared JBAIDS Tularemia Detection Kit (K072547). The first table outlines the similarities between the two systems and the second table outlines the differences.

Table 1. Similarities between the New Device and the Predicate

Element	New Device: JBAIDS Tularemia Detection Kit with addition of Platinum Path Sample Purification Kit	Predicate: JBAIDS Tularemia Detection Kit (K072547)
Intended Use	Presumptive identification of Tularemia infection through the detection of a DNA sequence unique to *Francisella tularensis*. Results are used in conjunction with clinical information, culture, and other laboratory tests as an aid in the diagnosis individuals presenting with signs and symptoms of pneumonic or typhoidal tularemia.	Same
Technology	Real-time PCR using hydrolysis probes	Same
Organism Detected	Qualitative *in vitro* detection of *Francisella tularensis* DNA	Same
Specimen Types	Whole blood (collected in 3.2% sodium citrate), sputum collected aseptically from individuals greater than 18 years of age suspected of having tularemia, blood culture (grown in soybean-casein digest broth) or bacterial culture (grown on blood agar)	Same
Platform	JBAIDS Instrument	Same
Time Required for Analysis of Specimen	Less than 3 hours	Same

Table 2. Differences between the New Device and the Predicate

Element	New Device: JBAIDS Tularemia Detection Kit with addition of Platinum Path Sample Purification Kit	Predicate: JBAIDS Tularemia Detection Kit (K072547)
DNA Extraction Methods	Whole blood purified with IT *1-2-3*™ Platinum Path or IT *1-2-3*™ QFLOW^{dna} Sample Purification Kits (or validated equivalent):	Whole blood purified with IT *1-2-3*™ QFLOW^{dna} Sample Purification Kit (or validated equivalent).
	Sputum purified with IT *1-2-3*™ Platinum Path or IT *1-2-3*™ VIBE Sample Purification Kits (or validated equivalent).	Sputum purified with IT *1-2-3*™ VIBE Sample Purification Kits (or validated equivalent).
	Blood culture purified with IT *1-2-3*™ SWIPE Sample Purification Kit (or validated equivalent).	Same
	Direct bacterial culture purified with IT *1-2-3*™ Platinum Path or IT *1-2-3*™ SWIPE Sample Purification Kit (or validated equivalent).	Direct bacterial culture purified with IT *1-2-3*™ SWIPE Sample Purification Kit (or validated equivalent).

Summary of Performance Data

Clinical Performance

True clinical specimens from patients infected with *Francisella tularensis* (tularemia), are not available for testing due to the extreme rarity of natural infection with this organism. Therefore, two clinical evaluations using surrogate specimens were performed to validate the use of the IT *1-2-3*™ Platinum Path Sample Purification Kit with the JBAIDS Tularemia Detection Kit.

Testing of Surrogate Whole Blood Clinical Specimens

One hundred (100) surrogate whole blood specimens were prepared using prospectively collected specimens that were collected from febrile volunteers from November of 2012 into April of 2013. Fifty (50) of the specimens were spiked with inactivated *F. tularensis* at concentrations near and above the system LoD, while the remaining 50 specimens were not spiked with *F. tularensis*. The level of inactivated *F. tularensis* used to spike these samples was relative to the LoD (1500 CFU/mL) established for Platinum Path-purified whole blood specimens.

Once spiked, samples were then processed using both the new nucleic acid extraction method (Platinum Path) and the original nucleic acid extraction method (IT *1-2-3*™ QFLOW^{dna} Sample Purification Kit; QFLOW^{dna}) followed by testing with the JBAIDS Tularemia Detection Kit. JBAIDS operators were blinded to the analyte content of the samples. Table 3 presents the Positive Percent Agreement (PPA) and Negative Percent Agreement (NPA) for the surrogate whole blood specimen testing. The results obtained with the Platinum Path processed samples were compared to the results obtained with the

QFLOW^{dna} processed samples. The JBAIDS result for a sample purified using from the QFLOW^{dna} kit was considered the correct result. The final Tularemia interpretation for samples purified using the Platinum Path kit had a positive percent agreement (PPA) of 100% as compared to samples purified using the QFLOW^{dna} kit (50/50; 95% CI = 92.9-100%). The final JBAIDS Tularemia interpretation for samples purified using Platinum Path was negative for 50 out of 50 samples that were negative when purified using QFLOW^{dna}. This represents a negative percent agreement (NPA) of 100% (50/50; 95% CI = 92.9-100%). Using samples spiked near the LoD for samples purified with the Platinum Path kit (1500 CFU/mL), the IT *1-2-3* QFLOW^{dna} and Platinum Path Sample Purification Kits performed equivalently with respect to detection of *F. tularensis* in surrogate whole blood specimens tested with the JBAIDS Tularemia Detection Kit.

Table 3. JBAIDS Tularemia Detection Kit Performance on Spiked Whole Blood Samples Processed with the IT *1-2-3* Platinum Path and QFLOW^{dna} Sample Purification Kits

Positive Agreement				Negative Agreement			
QFLOW + Platinum Path +	**QFLOW + Platinum Path -**	**PPA**	**95% CI[a]**	**QFLOW - Platinum Path -**	**QFLOW - Platinum Path +**	**NPA**	**95% CI**
50	0	100% (50/50)	92.9-100%	50	0	100% (50/50)	92.9-100%

[a] C.J. Clopper and E.S. Pearson. 1934. The use of confidence or fiducial limits illustrated in the case of the binomial. Biometrika 26:404-413.

Testing of Surrogate Sputum Clinical Specimens

One hundred (100) surrogate specimens were prepared using frozen residual sputum specimens. Fifty (50) of the specimens were spiked with inactivated *F. tularensis* at concentrations near and above the system LoD, while the remaining 50 specimens were not spiked with *F. tularensis*. Samples were then processed using both the new nucleic acid extraction method (Platinum Path) and the original nucleic acid extraction method (IT *1-2-3*™ VIBE Sample Purification Kit) followed by testing with the JBAIDS Tularemia Detection Kit. JBAIDS operators were blinded to the analyte content of the samples. Table 4 presents the Positive Percent Agreement (PPA) and Negative Percent Agreement (NPA) for the surrogate sputum specimen testing. The results obtained with the Platinum Path processed samples were compared to the results obtained with the VIBE processed samples. The JBAIDS result for a sample purified using from the VIBE kit was considered the correct result. The final Tularemia result for samples purified using the Platinum Path kit had a positive percent agreement (PPA) of 100% as compared to samples purified using VIBE (49/49; 95% CI = 92.8-100%). The final JBAIDS Tularemia result for samples purified using Platinum Path was negative for 49 out of 51 samples that were negative when purified using VIBE. This represents a negative percent agreement (NPA) of 96.1% (49/51; 95% CI = 86.5-99.5%). The IT *1-2-3* VIBE and Platinum Path Sample Purification Kits performed equivalently with respect to detection of *F. tularensis* in surrogate sputum specimens tested with the JBAIDS Tularemia Detection Kit.

Table 4. JBAIDS Tularemia Detection Kit Performance on Spiked Sputum Samples Processed with the IT *1-2-3* Platinum Path and VIBE Sample Purification Kits

Positive Agreement				Negative Agreement			
VIBE + Plat Path +	VIBE + Plat Path -	PPA	95% CI[a]	VIBE - Plat Path -	VIBE - Plat Path +	NPA	95% CI[a]
49	0	100% (49/49)	92.8-100%	49	2[b]	96.1% (49/51)	86.5-99.5%

[a] C.J. Clopper and E.S. Pearson. 1934. The use of confidence or fiducial limits illustrated in the case of the binomial. Biometrika 26:404-413.

[b] False positive results obtained for one unspiked sample processed with Platinum Path, and for one sample spiked at the 1× LoD level (positive result after Platinum Path processing, but negative after VIBE processing). When a sample is spiked at the 1× LoD level, ≥95% of results are expected to be positive. Occasional negative results are therefore expected (approximately 1 out of 20), with the consequence in this case of a false positive comparative result for a sample spike at the 1× LoD level.

Selected Analytic Studies

Limit of Detection

The originally established LoD of 300 CFU/mL in whole blood purified using the IT *1-2-3* QFLOW^{dna} Sample Purification Kit could not be confirmed using the Platinum Path Sample Purification Kit. Therefore, the system LoD for whole blood samples was increased by five-fold to 1500 CFU/mL. Twenty out of 20 independent whole blood specimens spiked with *F. tularensis* at the new LoD level and processed with the IT *1-2-3* Platinum Path Sample Purification Kit were detected with the JBAIDS Tularemia Detection Kit, establishing the new system LoD of 1500 CFU/mL *F. tularensis* in whole blood.

Nineteen (19) out of 20 independent sputum specimens spiked with *F. tularensis* at the LoD level and processed with the IT *1-2-3* Platinum Path Sample Purification Kit were detected with the JBAIDS Tularemia Detection Kit. This confirmed the LoD of 2000 CFU/mL in sputum that was originally established for sputum samples processed using the IT *1-2-3* VIBE Sample Purification Kit.

Table 5. Confirmation of the *F. tularensis* LoDs for Platinum Path-Purified Whole Blood and Sputum Samples Tested with the JBAIDS Tularemia Detection Kit

Sample Matrix	Spiked *F. tularensis* Concentration (CFU/mL)	# Positive	% Positive	Tularemia Target Assay Mean Cp +/- Std Dev
Whole Blood	1500[a]	20/20	100.0%	36.50 ± 1.81
Sputum	2000	19/20	95.0%	36.47 ± 1.70

[a] The JBAIDS Tularemia LoD determined in Platinum Path-purified whole blood samples is five-fold greater (indicating decreased sensitivity) than the originally established JBAIDS Tularemia LoD determined in QFLOW^{dna}-purified whole blood samples.

Reproducibility

A multicenter study was performed to determine the overall system reproducibility when whole blood and sputum samples were processed with the IT *1-2-3* Platinum Path Sample Purification Kit prior to testing with the JBAIDS Tularemia Detection Kit.

A panel of 12 blood samples was tested twice each day for four days at each of three testing sites. The panel contained four samples spiked with inactivated *F. tularensis* at a medium positive (5× LoD) level, four samples spiked at a low positive level (1× LoD), and four samples that were not spiked. The level of inactivated *F. tularensis* used to spike these samples was relative to the system LoD (1500 CFU/mL) established for Platinum Path-purified whole blood specimens. Results for whole blood testing are summarized in Table 6. Samples spiked *F. tularensis* at the low positive (1× LoD) level yielded final positive results 86.5% of the time overall. Examination of Cp values indicates these samples were likely under-spiked to approximately the 0.5× LoD level, where detection is expected to be below 95%. Detection at this low positive level was reproducibly less than 100% across the sites, and the JBAIDS Tularemia Detection System is reproducible when used to test whole blood samples processed with the IT *1-2-3* Platinum Path Sample Purification Kit.

Table 6. Reproducibility of the Tularemia Target Assay in the JBAIDS Tularemia Detection Kit for Whole Blood Samples Purified with the IT *1-2-3* Platinum Path Purification Kit

Blood Spike Level[a]	Test Location	Tularemia Target							
		Number Positive	Number Uncertain	Number Negative	% Agreement with Expected Result	95% CI	Mean Cp[b]	Std Dev	%CV
Medium Positive (5× LoD)	Site 1	32/32	0/32	0/32	100%		35.16	0.77	2.19
	Site 2	32/32	0/32	0/32	100%		35.83	1.40	3.91
	Site 3	32/32	0/32	0/32	100%		33.88	1.34	3.96
	All Sites	**96/96**	**0/96**	**0/96**	**100%**	**96.2-100**	**35.00**	**1.43**	**4.09**
Low Positive (1× LoD)	Site 1	28[c]/32	0/32	4[d]/32	87.5%		38.47	2.31	6.00
	Site 2	24[e]/32	5[f]/32	3/32	75%		39.38	2.32	5.89
	Site 3	31[g]/32	0/32	1/32	96.9%		36.53	2.32	6.35
	All Sites	**83/96**	**5/96**	**8/96**	**86.5%[h]**	**78.0-92.6**	**38.13**	**2.59**	**6.79**
Negative	Site 1	0/32	0/32	32/32	100%				
	Site 2	0/32	0/32	32/32	100%				
	Site 3	0/32	0/32	32/32	100%				
	All Sites	**0/96**	**0/96**	**96/96**	**100%**	**96.2-100**			

[a] The level of inactivated *F. tularensis* used to spike these samples was relative to the reset system LoD (1500 CFU/mL) established for Platinum Path-purified whole blood specimens.
[b] Cp values included for the samples that amplified only.
[c] Three results were initially uncertain but were positive when retested.
[d] Two results were initially uncertain but were negative when retested.
[e] Eight results were initially uncertain but were positive when retested.
[f] Five results were initially uncertain and were uncertain when retested.

[g]Three results were initially uncertain but were positive when retested.
[h] Samples spiked at the low positive level (1× LoD) yielded final positive results 86.5% of the time overall, with retesting required for initial uncertain results reproducibly observed at all three sites. Examination of Cp values indicates these samples were likely under-spiked to approximately the 0.5× LoD level, where detection is expected to be below 95%.

A panel of 9 sputum samples was similarly tested twice each day for five days at each of three testing sites. This panel contained three samples spiked with inactivated *F. tularensis* at a medium positive (5×LoD) level, three samples spiked at a low positive level (1×LoD), and three samples that were not spiked. Results for sputum testing are summarized in Table 7. The detection rate was ≥97.8% for all sputum samples containing *F. tularensis* spiked near or above the LoD, and there were no false positive results for unspiked samples. The JBAIDS Tularemia Detection System is reproducible when used to test sputum samples processed with the IT *1-2-3* Platinum Path Sample Purification Kit.

Table 7. Reproducibility of the Tularemia Target Assay in the JBAIDS Tularemia Detection Kit for Sputum Samples Purified with the IT *1-2-3* Platinum Path Purification Kit

Sputum Spike Level	Test Location	Tularemia Target							
		Number Positive	Number Uncertain	Number Negative	% Agreement with Expected Result	95% CI	Mean Cp[a]	Std Dev	%CV
Medium Positive (5× LoD)	Site 1	30/30	0/30	0/30	100%		35.35	1.46	4.13
	Site 2	30/30	0/30	0/30	100%		34.65	0.66	1.90
	Site 3	30/30	0/30	0/30	100%		34.37	0.53	1.54
	All Sites	**90/90**	**0/90**	**0/90**	**100%**	**96.0-100**	**34.79**	**1.05**	**3.02**
Low Positive (1× LoD)	Site 1	28[b]/30	1[c]/30	1/30	93.3%		39.19	2.62	6.69
	Site 2	30[d]/30	0/30	0/30	100%		38.49	2.37	6.16
	Site 3	30[e]/30	0/30	0/30	100%		38.15	2.22	5.82
	All Sites	**88/90**	**1/90**	**1/90**	**97.8%**	**92.2-99.7**	**38.60**	**2.43**	**6.30**
Negative	Site 1	0/30	0/30	30/30	100%				
	Site 2	0/30	0/30	30/30	100%				
	Site 3	0/30	0/30	30/30	100%				
	All Sites	**0/90**	**0/90**	**90/90**	**100%**	**96.0-100**			

[a] Cp values included for the samples that amplified only.
[b] Four results were initially uncertain but were positive when retested.
[c] One result was initially uncertain and was uncertain when retested.
[d] Two results were initially uncertain but were positive when retested.
[e] One result was initially uncertain and was positive when retested.

Detection of Direct Culture Samples Processed with the IT 1-2-3 Platinum Path Sample Purification Kit

F. tularensis colonies can be detected using a Platinum Path protocol to process the colonies followed by testing with the JBAIDS Tularemia Detection Kit. Ten *F. tularensis*

colonies were purified alongside ten non- *F. tularensis* colonies. All ten *F. tularensis* colonies were detected with the JBAIDS Tularemia Detection Kit, while the non- *F. tularensis* colonies were not detected.

Table 8. Tularemia Target Detection from Colonies Purified with Platinum Path

Colony Type	Tularemia Target		
	Positive Results/Total	Cp (cycles)	
		Mean	SD
F. tularensis	**10/10**	21.00	0.31
Non- F. tularensis	**0/10**	-	-

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

CYNTHIA PHILLIPS, Ph.D.
MANAGER, JBAIDS REGULATED PRODUCTS
BIOFIRE DIAGNOSTICS, INC.
390 WAKARA WAY
SALT LAKE CITY UT 84108

July 31, 2013

Re: K131936
Trade/Device Name: JBAIDS Tularemia Detection Kit
Regulation Number: 21 CFR 866.3280
Regulation Name: *Francisella tularensis* Serological Reagents
Regulatory Class: II
Product Code: OEH
Dated: June 25, 2013
Received: June 27, 2013

Dear Dr. Phillips:

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 (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. 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.

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 Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulations (21 CFR Parts 801 and 809), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Uwe Scherf -S for

Sally A. Hojvat, M.Sc., Ph.D.
Director, Division of Microbiology Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): ___K131936_____
Device Name: JBAIDS Tularemia Detection System

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The diagnosis of tularemia must be made based on history, signs, symptoms, exposure likelihood, and other laboratory evidence in addition to the identification of the target either from colonies, blood culture, whole blood or sputum specimens.

The JBAIDS Tularemia Detection Kit is intended for use by trained clinical laboratory personnel who have received specific training on the use of the JBAIDS Tularemia Detection Kit. The level of *F. tularensis* that would be present in blood or sputum from individuals with early systemic or pneumonic infection is unknown. Due to the difficulty in obtaining clinical specimens, this assay was not evaluated with blood or sputum from individuals presenting with signs and symptoms of tularemia who have subsequently developed pneumonic or typhoidal tularemia pneumonic or typhoidal tularemia.

Prescription Use ___x____ (Part 21 CFR 801 Subpart D) AND/OR Over-the-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE—CONTINUE

ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of *In Vitro* Diagnostics and Radiological Health (OIR)

John Hobson -S
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