January 22, 2018

Techlab, Inc.
Donna Link
Director Regulatory and Compliance
2001 Kraft Drive
Blacksburg, Virginia 24060

Re: K173217
Trade/Device Name: Campylobacter Quik Chek
Regulation Number: 21 CFR 866.3110
Regulation Name: Campylobacter fetus serological reagents
Regulatory Class: Class I
Product Code: LQP
Dated: September 29, 2017
Received: October 25, 2017

Dear Donna Link:

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 Part 801 and Part 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.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Ribhi Shawar -S
For

Uwe Scherf, M.Sc., Ph.D.
Director
Division of Microbiology Devices
Office of In Vitro Diagnostics
and Radiological Health
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K173217

Device Name
CAMPYLOBACTER QUIK CHEK

Indications for Use *(Describe)*

The CAMPYLOBACTER QUIK CHEK™ test is a rapid membrane enzyme-linked immunosorbent assay for the qualitative detection of a Campylobacter-specific antigen in human fecal specimens. The CAMPYLOBACTER QUIK CHEK™ test is designed to detect C. jejuni and C. coli from patients with signs and symptoms of gastroenteritis. The test is intended for use with preserved fecal specimens in transport media and unpreserved fecal specimens. Test results should be considered in conjunction with clinical findings and patient history.

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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***CAMPYLOBACTER QUIK CHEK*™ 510(k) SUMMARY**

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

Applicant/Contact Information:

Date Prepared:	January 22, 2018
Name:	TECHLAB, Inc.
Address:	2001 Kraft Drive Corporate Research Center Blacksburg, VA 24060 USA
Contact Person:	Donna T. Link
Phone Number:	540-953-1664
Email:	dlink@techlab.com

1.1 Manufacturing Facility Address

TECHLAB, Inc.
20 Corporate Drive
Radford, VA 24141 USA

1.2 Product and Trade Name of the Device

CAMPYLOBACTER QUIK CHEK™

1.3 Common Name or Classification Name

Campylobacter spp. detection test

1.4 Classification and Regulation

Class I
21 CFR 866.3110; *Campylobacter fetus* serological reagents

1.5 Product Code

LQP – *Campylobacter* spp.

1.6 Panel

83 Microbiology

1.7 Reason for Premarket Notification

The development of a new rapid membrane enzyme immunoassay for the qualitative detection of *Campylobacter spp.* in a single use cassette.

Intended Use

The *CAMPYLOBACTER QUIK CHEK*™ test is a rapid membrane enzyme-linked immunosorbent assay for the qualitative detection of a *Campylobacter*-specific antigen in human fecal specimens. The *CAMPYLOBACTER QUIK CHEK*™ test is designed to detect *C. jejuni* and *C. coli* from patients with signs and symptoms of gastroenteritis. The test is intended for use with preserved fecal specimens in transport media and unpreserved fecal specimens. Test results should be considered in conjunction with clinical findings and patient history.

Explanation

Worldwide, *Campylobacter* species are the most common cause of bacterial gastroenteritis, with 400-500 million cases of diarrhea each year. Infants in developing countries are at even greater risk, as are travelers to those countries. *Campylobacter*–associated gastroenteritis is estimated to affect nearly 1 million people a year in the USA. In approximately 1 of 1000 cases, *Campylobacter jejuni* is closely linked to the subsequent development of Guillian-Barre Syndrome, an acute auto-immune paralysis. *C. jejuni* infection has also been associated with reactive arthritis in both children and adults. When individuals with severe symptoms of gastroenteritis seek medical help, the clinician is faced with multiple possible causes that can present with similar clinical features (e.g., diarrhea, nausea, vomiting, fever, abdominal pain) but that require very different, often conflicting, types of treatment.

For *Campylobacter*, the current standard for identification is bacterial culture followed by microscopic examination of the organisms. Although this traditional method is straightforward, it has two major limitations. First, pathogenic species of *Campylobacter* are microaerophilic or strictly anaerobic, so that exposure of culture or feces to environmental oxygen leads to death or inactivation of the bacteria. Thus, during transport or storage of specimens under aerobic conditions, the number of viable organisms can decrease, leading to potentially inaccurate culture results. Second, *Campylobacter* species are slow-growing, requiring from 48-72 hours before reaching a point where the culture can safely be reported as negative. Such delays can leave the clinician in a quandary and the patient with non-specific, ineffective, or even inappropriate treatment.

The *CAMPYLOBACTER QUIK CHEK*™ test allows detection of *Campylobacter jejuni* and *Campylobacter coli*, the species most commonly associated with human disease, in less than 30 minutes. Furthermore, the *CAMPYLOBACTER QUIK CHEK*™ test does not rely on bacterial viability, and can be performed on the bench-top with samples that have been exposed to air.

Device Description

The *CAMPYLOBACTER QUIK CHEK*™ test uses antibodies that recognize a *Campylobacter*-specific antigen in human fecal samples. The device contains a *Reaction Window* with two vertical lines of immobilized antibodies. The test line (“T”) contains antibodies against a *Campylobacter*-specific antigen. The control line (“C”), contains anti-IgG antibodies. The *Conjugate* consists of antibodies to a *Campylobacter*-specific antigen coupled to horseradish peroxidase. To perform the test, a fecal specimen is added to a tube containing a mixture of *Diluent* and *Conjugate*. The diluted sample-conjugate mixture is added to the *Sample Well* and the device is allowed to incubate at room temperature for 15 minutes. During the incubation, the *Campylobacter*-specific antigens in the sample bind to the antibody-peroxidase conjugate. The antigen-antibody complexes migrate through a filter pad to a membrane where they are captured by the immobilized anti-*Campylobacter* antibodies in the line. The *Reaction Window* is subsequently washed with *Wash Buffer*, followed by the addition of *Substrate*. After a 10-minute incubation, the “T” reaction is examined visually for the appearance of a vertical blue line. A blue line indicates a positive test. A positive “C” reaction, indicated by a vertical blue line, monitors/confirms that the sample and reagents were added correctly, the reagents were active at the time of performing the assay, and that the sample migrated properly through the

Membrane Device. It also confirms the reactivity of the other reagents associated with the assay and that the results are valid.

Materials Provided

- ***Membrane Devices*** – 25, each pouch contains 1 device
- ***Conjugate* (2.5 mL)** – Antibody to a *Campylobacter*-specific antigen coupled to horseradish peroxidase in a buffered protein solution
- ***Diluent* (22 mL)** – Buffered protein solution with graduated dropper assembly
- ***Positive Control* (2 mL)** – *Campylobacter*-specific antigen in a buffered protein solution
- ***Wash Buffer* (12 mL)** – Buffered solution with graduated dropper assembly
- ***Substrate* (3.5 mL)** – Solution containing tetramethylbenzidine
- ***Disposable plastic transfer pipettes*** – graduated at 25 µL, 100 µL, 200 µL, 300 µL, 400 µL and 500 µL

The predicate device (Immuno*Card* STAT!® CAMPY) and the *CAMPYLOBACTER QUIK CHEK*™ test both detect *Campylobacter* spp. (*C. jejuni* and *C. coli*) in fecal specimens and are substantially equivalent in principle. The following table shows a comparison of both devices.

Similarities		
Item	Device K173217	Predicate K090700
Indications for use	The *CAMPYLOBACTER QUIK CHEK*™ test is a rapid membrane enzyme-linked immunosorbent assay for the qualitative detection of a *Campylobacter*-specific antigen in human fecal specimens. The *CAMPYLOBACTER QUIK CHEK* test is designed to detect *C. jejuni* and *C. coli* from patients with symptoms of gastroenteritis. The test is intended for use with unpreserved human fecal specimens and fecal specimens that are in transport media. Test results should be considered in conjunction with clinical findings and patient history.	Immuno*Card* STAT! CAMPY is an immunochromatographic rapid test for the qualitative detection of specific *Campylobacter* antigens in human stool. Immuno*Card* STAT! CAMPY detects *C. jejuni* and *C. coli* in human stool, where stool may be either unpreserved or preserved in Cary-Blair-based transport media. Test results are to be used in conjunction with information available from the patient clinical evaluation and other diagnostic procedures.
Measured analyte	Detection of *Campylobacter*-specific antigens (*C. jejuni* and *C. coli*)	Detection of *Campylobacter*-specific antigens (*C. jejuni* and *C. coli*)
Type of Test	Qualitative	Same
Controls	Positive and negative control included in the kit Internal “C” Control line	Same
Format	Single Use Membrane Cassette	Same
Target Population	Persons suspected of having *Campylobacter* infection	Same
Storage	Refrigerated (2°C – 8°C)	Same

There are no differences between the subject device and the predicate(s) with respect to indications and intended use.

Differences		
Item	Device K173217	Predicate K090700
Specimen Type	Fecal specimens in Cary-Blair and C&S Transport Media	Fecal specimens in Cary-Blair Transport Media
Time to Result	<30 minutes	< 25 minutes
Antibody Format	Monoclonal/Polyclonal	Monoclonal/Monoclonal

Summary of Performance Data

Prospective Study

The performance of the *CAMPYLOBACTER QUIK CHEK*™ test was evaluated at 4 independent sites. Prospective incoming fecal specimens were collected and tested by culture and the *CAMPYLOBACTER QUIK CHEK*™ test. The following table shows a summary of the clinical performance of the *CAMPYLOBACTER QUIK CHEK*™ test for all 4 sites combined. The results of the study show that the *CAMPYLOBACTER QUIK CHEK*™ test exhibited a sensitivity of 97.1%, and a specificity of 99.1% with culture.

Age and Gender Distribution

Age information was available for 1552 patients. The ages ranged from less than 1 year to 100 years. Of the 1552 patients, 15.7% were ≤ 18 years. The gender identification was 38.7% females and 61.3% males. No difference in test performance was observed based on patient age or gender.

***CAMPYLOBACTER QUIK CHEK*™ test versus Culture**

N = 1552	Culture Positive	Culture Negative
***CAMPYLOBACTER QUIK CHEK*™ Positive**	**34**	**13***
***CAMPYLOBACTER QUIK CHEK*™ Negative**	**1****	**1504**

		95% Confidence Limits
Sensitivity	97.1%	85.5% - 99.9%
Specificity	99.1%	98.5% - 99.5%

The 14 discrepant specimens were further characterized by additional testing at TECHLAB. This testing included an FDA-cleared commercial Microassay well EIA, an FDA-cleared commercial molecular test, in-house PCR (detecting the 16s rRNA gene of *Campylobacter* spp., and species-specific identification), and bidirectional sequencing.

***** Nine of the 13 specimens that were culture negative and *CAMPYLOBACTER QUIK CHEK*™ test positive were confirmed to be positive for *C. jejuni* with all test methods.
Two of the 13 specimens that were culture negative and *CAMPYLOBACTER QUIK CHEK*™ test positive were confirmed to be positive with the commercial EIA, in-house PCR, and bidirectional sequencing.

One of the 13 specimens that was culture negative and *CAMPYLOBACTER QUIK CHEK*™ test positive was confirmed to be positive with an FDA-cleared commercial molecular test, in-house PCR and bidirectional sequencing.
One specimen that was culture negative and *CAMPYLOBACTER QUIK CHEK*™ test positive was confirmed to be positive for *C. upsaliensis* (an important pathogen) by species-specific PCR and sequencing.

** The one specimen that was culture positive and *CAMPYLOBACTER QUIK CHEK*™ test negative was confirmed to be negative for *C. jejuni* or *C. coli* with all test methods.

Retrospective Study

Supplemental testing was performed on 30 retrospective positive specimens. The patient ages ranged from less than 11 months to 74 years. All retrospective specimens were *Campylobacter* spp. culture positive and were further characterized as *Campylobacter* spp. positive by an FDA-cleared commercial Microassay well EIA, an FDA-cleared commercial molecular test, in-house PCR (detecting the 16s rRNA gene of *Campylobacter* spp., and species-specific identification), and bidirectional sequencing. These specimens were then tested in the *CAMPYLOBACTER QUIK CHEK*™ test. All 30 specimens tested positive for *Campylobacter* spp. by all methods, yielding 100% correlation with all test methods.

Reproducibility

The reproducibility of the *CAMPYLOBACTER QUIK CHEK*™ test was determined using 8 fecal specimens that were coded to prevent their identification during testing. Testing was performed at 2 independent laboratories and on-site at TECHLAB, Inc. The samples included 2 negative samples, 2 high negative samples, 2 low positive samples and 2 moderate positive samples. The samples were tested in triplicate twice a day over a 5-day period by multiple technicians at each site using 2 different kit lots. A positive and negative control was run with each panel of the masked samples. The results from each laboratory were submitted to TECHLAB, Inc. and compared with in-house results. The results were consistent among the different locations, and exhibited a correlation of 100%. The samples produced the expected results 100% of the time.

Analytical Sensitivity

The analytical sensitivity of the test was determined by using *C. jejuni* and *C. coli* whole organism culture preparations in a sample matrix. The concentration of *C. jejuni* and *C. coli* organisms in fecal matrix at which specimens are positive by the *CAMPYLOBACTER QUIK CHEK*™ test 95% of the time is the assay Limit of Detection (LoD).

The Limit of Detection (LoD) for the *CAMPYLOBACTER QUIK CHEK*™ test with raw fecal samples was established at 8.39×10^4 CFU/mL (1271 CFU/test) for *C. jejuni*. For specimens in Protocol™ Cary Blair media, the LoD was established at 1.78×10^5 CFU/mL (2781 CFU/test) for *C. jejuni*. For specimens in Protocol™ C&S media, the LoD was established at 7.25×10^4 CFU/mL (1133 CFU/test) for *C. jejuni*.

The Limit of Detection (LoD) for the *CAMPYLOBACTER QUIK CHEK*™ test with raw fecal samples was established at 7.70×10^5 CFU/mL (11667 CFU/test) for *C. coli*. For specimens in Protocol™ Cary Blair media, the LoD was established at 2.22×10^6 CFU/mL (34688 CFU/test) for *C. coli*. For specimens in Protocol™ C&S media, the LoD was established at 1.56×10^6 CFU/mL (24375 CFU/test) for *C. coli*.

Analytical Specificity (Cross Reactivity)

The *CAMPYLOBACTER QUIK CHEK*™ test was evaluated for cross-reactivity with common intestinal organisms and viruses listed below. None of the organisms or viruses were shown to interfere with the performance of the *CAMPYLOBACTER QUIK CHEK*™ test.

Acinetobacter baumannii	*Aeromonas hydrophila*	*Bacillus cereus*
Bacillus subtilis	*Bacteroides fragilis*	*Campylobacter concisus*
Campylobacter fetus	*Candida albicans*	*Citrobacter freundii*
Clostridium bifermentans	*Clostridium difficile*	*Clostridium perfringens*
Edwardsiella tarda	*Enterobacter cloacae*	*Enterococcus faecalis*
Escherichia coli	*Escherichia coli EIEC*	*Escherichia coli EPEC*
Escherichia coli ETEC	*Escherichia coli* O157:H7 (non-toxigenic)	
Escherichia coli O157:H7 (toxigenic)	*Escherichia fergusonii*	*Escherichia hermanii*
Helicobacter pylori	*Klebsiella pneumoniae*	*Lactobacillus acidophilus*
Lactococcus lactis	*Listeria monocytogenes*	*Peptostreptococcus anaerobius*
Plesiomonas shigelloides	*Porphyromonas asaccharolytica*	*Prevotella melaninogenica*
Proteus vulgaris	*Pseudomonas aeruginosa*	*Pseudomonas fluorescens*
Salmonella enterica typhimurium	*Serratia marcescens*	*Shigella dysenteriae*
Shigella flexneri	*Shigella sonnei*	*Staphylococcus aureus*
Staphylococcus aureus (Cowan's)	*Streptococcus agalactiae*	*Staphylococcus epidermidis*
Vibrio parahaemolyticus	*Yersinia enterocolitica*	

Adenovirus Type 1, 2, 3, 5, 40, 41	Human Coronavirus	Coxsackievirus B2, B3, B4, B5
Echovirus 9, 11, 18, 22, 33	Enterovirus 68, 69, 70, 71	Norovirus
Human Rotavirus		

Campylobacter species that were shown to be reactive with the *CAMPYLOBACTER QUIK CHEK*™ test.
C. helveticus (strain 54661) was found to be positive at 3.08 x 10^6 CFU/mL (4 x LoD of *C. coli*)
C. lari (strain 23947) was found to be positive at 3.08 x 10^6 CFU/mL (4 x LoD of *C. coli*)
C. upsaliensis (strain 14913) was found to be positive at 1.54 x 10^6 CFU/mL (2 x LoD of *C. coli*)

Inclusivity Study

The specificity of the *CAMPYLOBACTER QUIK CHEK*™ test was evaluated using several strains of *Campylobacter jejuni* and *Campylobacter coli.* All strains listed generated positive results when tested.

C. coli strains: 11283, 10956, 17755, 36994, 53138
C. jejuni sub-species *jejuni* strains: 11284, 6951, 12081, 29411, 38106
C. jejuni sub-species *doylei* strain: 24567

Interfering Substances (U.S. Formulation)

The following substances had no effect on positive or negative *CAMPYLOBACTER QUIK CHEK*™ test results analyzed at the concentrations indicated:
Barium sulfate (5% w/v), Benzalkonium Chloride (1% w/v), Ciprofloxacin (0.25% w/v), Ethanol (1% w/v), Hog gastric mucin (3.5% w/v), Human blood (40% v/v), Hydrocortisone (1% w/v), Imodium® (5% v/v), Kaopectate® (5% v/v), Leukocytes (0.05% w/v), Maalox® Advanced (5% v/v), Mesalazine (10% w/v), Metronidazole (0.25% w/v), Mineral Oil (10% w/v), Mylanta® (4.2 mg/mL), Naproxen Sodium (5% w/v), Nonoxynol-9 (40% w/v), Nystatin (1% w/v), Palmitic Acid/Fecal Fat (40% w/v), Pepto-Bismol® (5% v/v), Phenylephrine (1% w/v), Polyethylene glycol 3350 (10% w/v), Prilosec OTC® (5 µg/mL), Sennosides (1% w/v), Simethicone (10% w/v), Steric Acid/Fecal Fat (40% w/v), Tagamet® (5 µg/mL), TUMS® (50 µg/mL), Human Urine (5% v/v), and Vancomycin (0.25% w/v).

Prozone

To ensure that a high concentration of *Campylobacter* antigen does not interfere with a positive reaction in the *CAMPYLOBACTER QUIK CHEK*™ test, high positive samples were prepared by spiking a negative fecal pool at a concentration possibly observed in clinical specimens. A total of 5 different dilutions of *C. jejuni* and *C. coli* whole organism culture preparation, up to and including the clinically observed high concentration, were prepared and tested in triplicate. The results demonstrated that there was no overall prozone effect, that elevated levels of antigen did not affect the detection of the antigen.

CONCLUSION

The conclusions drawn from the nonclinical and clinical tests demonstrate that the *CAMPYLOBACTER QUIK CHEK*™ test is as safe and as effective and performs as well or better than standard culture, and is equivalent to the predicate device in performance. The information submitted in this premarket notification is complete and supports a substantial equivalence decision.