510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY

A. 510(k) Number:

K173217

B. Purpose for Submission:

To obtain a substantial equivalence determination for the detection of *Campylobacter jejuni* and *Campylobacter coli* antigens in human stool.

C. Measurand:

Campylobacter jejuni and *Campylobactercoli* antigens

D. Type of Test:

Qualitative membrane enzyme immunoassay

E. Applicant:

TechLab Inc.

F. Proprietary and Established Names:

CAMPYLOBACTER QUIK CHEK

G. Regulatory Information:

1. Regulation section:

   21 CFR 866.3110 Camplobacter fetus serological reagents

2. Classification:

   I

3. Product code:

   LQP

4. Panel:

83 Microbiology

H. Intended Use:

1. Intended use(s):

   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

2. Indication(s) 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

3. Special conditions for use statement(s):

   - For prescription use only
   - Optimal results with the *CAMPYLOBACTER QUIK CHEK* test are obtained with specimens that are less than 96 hours old. If specimens are not assayed within this time period, they may be frozen.
   - Fecal specimens preserved in 10% Formalin, merthiolate formalin, sodium acetate formalin, or polyvinyl alcohol cannot be used.
   - The *CAMPYLOBACTER QUIK CHEK* test is qualitative. The intensity of the color should not be interpreted quantitatively.
   - No data exists on the effects of colonic washes, barium enemas, laxatives, or bowel preparations on the performance of the *CAMPYLOBACTER QUIK CHEK* test. All of these procedures can result in extensive dilution or the presence of additives that may affect test performance.

4. Special instrument requirements:

   None

I. Device Description:

The *CAMPYLOBACTER QUIK CHEK* test uses antibodies to *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 *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. The "T" reaction is examined visually for the appearance of a vertical blue line on the "T" side of the Reaction Window. A blue line indicates a positive test. A positive "C" reaction, indicated by a vertical blue line on the "C" side of the reaction window, 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. A positive "C" reaction also confirms the reactivity of the other reagents associated with the assay.

J. Substantial Equivalence Information:

1. Predicate device name(s):

   IMMUNOCARD STAT CAMPY

2. Predicate 510(k) number(s):

   K090700

3. Comparison with predicate:

Table 1. Comparison of the *CAMPYLOBACTER CHECK* to IMMUNOCARD STAT CAMPY

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*)

Similarities		
Item	Device K173217	Predicate K090700
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

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

K. Standard/Guidance Document Referenced (if applicable):

CLSI EP07-A2 Interference Testing In Clinical Chemistry; Approved Guideline - Second Edition

CLSI EP15-A3 User Verification of Precision And Estimation Of Bias; Approved Guideline - Third Edition

CLSI EP17-A2 Evaluation Of Detection Capability For Clinical Laboratory Measurement Procedures; Approved Guideline - Second Edition

L. Test Principle:

Lateral flow immunochromatographic assay

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. Precision/Reproducibility:

The reproducibility of the *CAMPYLOBACTER QUIK CHEK* test was determined using an eight member masked fecal specimen panel. The panel consisted of 2 negative, 2 high negative (just below C5), 2 low positive (just above LoD), and 2 moderate positive (2-3x higher than the C95) specimens. Each fecal specimen was spiked using a known concentration of *C. jejuni* whole organism to achieve the desired level. Testing was performed at 2 independent laboratories and on-site at TECHLAB, Inc. The Specimens were tested twice a day in triplicate over a five day

period by multiple technicians at each site using two different kit lots. Positive and negative controls were run with each sample panel of masked specimens. The result from each laboratory were submitted to TECHLAB Inc. and compared. The results were consistent among all three locations with100% reproducibility for all test panels.

b. *Linearity/assay reportable range:*

Not applicable

c. *Traceability, Stability, Expected values (controls, calibrators, or methods):*
The effect of specimen storage on antigen stability was evaluated for both fresh samples and samples in transport media. For the analysis, a total of 20 fecal specimens were tested with the *CAMPYLOBACTER QUIK CHEK* test. The fecal specimens consisted 10 *C. jejuni* low positive fecal samples (1-2 times C95 for whole organisms), 5 *C. jejuni* moderate positive fecal samples (2-3 times C95 for whole organism), and 5 *C. jejuni* high positive fecal samples (4-5 times C95 for whole organism). Both fresh samples and samples stored in Cary Blair and C&S transport media were tested.

For fresh samples, samples were stored between 2°C and 8°C and tested at 24 hour intervals for 120 hours. At the same time positive and negative controls were tested. The following transport media were used for the study: Thermo Scientific *Protocol* Cary Blair media and Meridian Bioscience Inc., *Para-Pak* C&S. As recommended in the package insert, Cary Blair and C&S samples were stored between 20°C and 30°C. Samples stored in transport media were tested at 24 hour intervals for 120 hours.

Positive samples remained positive throughout the study. Storage in transport media did not affect the stability of the samples. Based on these results, the recommended storage time for fresh samples is up to 120 hours between 2°C and 8°C, Cary Blair transport media is up to 96 hours between 20°C and 30°C and C&S transport media is up to 120 hours between 20°C-30°C based on the data and the package insert recommendation.

Freeze/Thaw:

Freeze/Thaw stability for raw specimens was demonstrated for six freeze/thaw cycle over a nine day period. A panel consisting of 20 masked raw stool samples were prepared and tested in duplicates; three true negative, two high negative (1-2 times belowC5 (whole organisms)), five low positives (1-2 times C95 (whole organisms)), six moderate positives (2-3 times C95 (whole organisms)) and four high positives (4-5 x LoD (whole organisms)) were tested in raw stool. Based on the data submitted, none of the speciemns converted from positive-to-negative or negative-to-positive after any of the freeze/thaw cycles. After six cycles freeze/thawing neither enhances nor impairs the performance of the CAMPYLOBACTER QUIK CHEK test.

d. Detection limit:

The limit of detection (LoD) for the *CAMPYLOBACTER QUIK CHEK* test was determined visually using whole organisms of both *C. jejuni* and *C. coli* spiked into unpreserved (raw stool) and preserved (Cary Blair and C&S media). The concentrations were calculated in colony forming units per milliliter (CFU/mL) and their equivalent in CFU/test by factoring in the dilutions and the final volume used in the assay. The LoD is the concentrations of organisms that yields a positive result 95% of the time and a negative result 5% of the time. See the LoDs in Table 2 listed by organisms and by stool (unpreserved and preserved).

Table 2. LoD for *C. jejuni* and *C. coli*

C. jejuni		*C. coli*	
CFU/mL	CFU/test	CFU/mL	CFU/test
Fecal Matrix			
8.4×10^4	1,300	7.7×10^5	11,700
Cary Blair			
1.8×10^5	2,800	2.2×10^6	34,700
C & S			
7.2×10^4	1,100	1.6×10^6	24,400

e. Analytical specificity:

The *CAMPYLOBACTER QUIK CHEK* test was evaluated for cross-reactivity with the bacteria and viruses listed below. *C. helveticus* (strain 54661) was found to be positive at 3.08×10^6 CFU/mL (4 x LoD of *C. coli*). *C. lari* (strain 23947) was found to be positive at 3.08×10^6 CFU/mL (4 x LoD of *C. coli*). *C. upsaliensis* (strain 14913) was found to be positive at 1.54×10^6 CFU/mL (2 x LoD of *C. coli*). All other strains were shown to not interfere with the performance of the *CAMPYLOBACTER QUIK CHEK* test. Bacteria was spiked at concentration of $>10^8$ CFU/mL and viruses at a range from $10^{3.3}$ to $10^{8.75}$ $TCID_{50}$ units per 0.2 mL.

Acinetobacter baumannii
Aeromonas hydrophila
Bacillus cereus
Bacillus subtilis
Bacteroides fragilis
Campylobacter concisus
Campylobacter fetus
Campylobacter hyointestinalis
Campylobacterhelveticus
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-
Escherichia coli O157:H7 (toxigenic)

toxigenic)
Escherichia fergusonii
Escherichia hermanii
Helicobacter pylori
Klebsiella pneumoniae
Lactobacillus acidophilus
Lactococcus lactis
Listeria monocytogenes
Peptostreptococcus anaerobius
Plesiomonas shigelloides
Prophyromonas asaccharolytica
Proteus vulgaris
Prevotella melaninogenica
Pseudomonas areuginosa
Pseudomonas fluorescens
Salmonella enterica typhimurium
Serratia marcescens
Shigella dysenteriae
Shigella flexneri
Shigella sonnei
Staphylococcus aureus
Staphylococcus aureus (Cowan's)
Staphylococcus epidermidis
Streptococcus agalactiae
Vibrio parahaemolyticus
Yersinia enterocolitica

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

The *CAMPYLOBACTER QUIK CHEK* test was evaluated for interfering substances with the substances and concentrations listed in Table 3. None of the substances where shown to interfere with the performance of the *CAMPYLOBACTER QUIK CHEK* test.

Table 3. Interfering Substances

Barium sulfate (5% w/v)	Benzalkonium Chloride (1% w/v)
Ciprofloxacin (0.25% w/v)	Hog gastric mucin (3.5% w/v)
Human blood (40% v/v)	Imodium® (5% v/v),
Kaopectate® (5% v/v)	Maalox® Advanced (5% v/v)
Mesalazine (10% w/v)	Metronidazole (0.25% w/v)
Mylanta® (4.2 mg/mL)	Naproxen Sodium (5% w/v)
Nonoxynol-9 (40% w/v)	Palmitic Acid/Fecal Fat (40% w/v)
Pepto-Bismol® (5% v/v)	Phenylephrine (1% w/v)
Priolsec OTC® (5 µg/mL)	Sennosides (1% w/v)
Simethicone (10% w/v)	Tagamet® (5 µg/mL) (40%w/v)
Tagamet® (5 µg/mL)	TUMS (50 µg/mL)
Human Urine (5% v/v)	Vancomycin (0.25% w/v)

Strain Reactivity Study

The sponsor tested the reactivity of the following *Campylobacter* stock cultures from different sources at 2x, 4x, and 8x the LoD of each species: *C. coli* strains 11283, 10956, 17755, 36994, 53138 and *C. jejuni* strains 11284, 6951, 12081, 29411, 38106, and 24567. All results were positive except for *C. coli* strain 53138 and 10956 which

was negative at 2x LoD and 4xLOD but positive at 8x LoD. *C. coli* strain 11283 was negative at 2x LoD but positive at 4x LOD and 8x LoD.

f. Assay cut-off:

Not applicable

g. Prozone:

The purpose of this study was to demonstrate that a high concentration of Camplobacter (antigen) does not interfere with a positive reaction in the *CAMPYLOBACTER QUIK CHEK* test. High samples were prepared by spiking a negative fecal pool with 5 X 10^7 whole organisms of *C. jejuni* and 2.4 X 10^8 whole organisms of *C. coli*. A total of 5 different dilutions of C. jejuni and C. coli whole organisms, were prepared and tested. Testing was performed in triplicate according to the Package Insert instructions. The results demonstrated that there was no overall hook affect, and that elevated levels of whole organism did not affect the detection or Campylobacter.

2. Comparison studies:

a. Method comparison with predicate device:

Not applicable

b. Matrix comparison:

Not applicable

3. Clinical studies:

a. Clinical Sensitivity:

Prospective Study

The performance of the *CAMPYLOBACTER QUIK CHEK* test was evaluated at four independent sites. The sensitivity and specificity for the *CAMPYLOBACTER QUIK CHEK* device was compared directly to culture results at all three sites. Prospective testing consisted of 1552 stool specimens tested in clinical microbiology laboratories at the Medical College of Wisconsin, Penn State Milton S. Hershey Medical Center, TriCore Reference Laboratories and Techlab, Inc.

The ages of patients ranged from less than 1 year to 100 Years with, 15.7% of the specimens coming from patients that were ≤ 18 years. Of the 1552 patients tested 38.7% were female and 61.3% were male. No difference in test performance was observed based on patient age or gender.

Table 4. 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.

Table 4. Clinical Perfomance of the CAMPYLOBACTER QUIK CHEK

	Culture Positive	Culture Negative
CAMPYLOBACTER QUIK CHEK Positive	**34**	**13***
CAMPYLOBACTER QUIK CHEK Negative	**1****	**1504**

Sensitivity (95% C.I.)	97.1% (85.5% - 99.9%)
Specificity (95% C.I.)	99.1%(98.5% - 99.5%)

* Nine of the specimens were confirmed to be positive for *C. jejuni* with all test methods.Two of the specimens were confirmed to be positive with the commercial EIA, in-house PCR, and bidirectional sequencing. One of the specimens was confirmed to be positive with an FDA-cleared commercial molecular test, in-house PCR and bidirectional sequencing. One of the specimen was confirmed to be positive for *C. upsaliensis* by species-specific PCR and sequencing.

** The one specimen was confirmed to be negative for *C. jejuni* or *C. coli* with all test methods.

Retrospective Study

Additional 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 by the *CAMPYLOBACTER QUIK CHEK* test. All 30 specimens tested positive for *Campylobacter* spp. by all methods, yielding 100% correlation with all test methods.

b. Clinical specificity:

See section M3a. above.

c. Other clinical supportive data (when a. and b. are not applicable):

Not applicable.

4. Clinical cut-off:

Not applicable.

5. Expected values/Reference range:

   Not applicable.

N. Proposed Labeling:

The labeling is sufficient and it satisfies the requirements of 21 CFR Parts 809.10

O. Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.