Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002
www.fda.gov

SPECIAL 510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY

I Background Information:

A 510(k) Number

K191442

B Applicant

Techlab, Inc.

C Proprietary and Established Names

CAMPYLOBACTER CHEK

D Regulatory Information

Product Code(s)	Classification	Regulation Section	Panel
LQP	Class I	21 CFR 866.3110 - *Campylobacter fetus* Serological Reagents	MI – Microbiology

II Review Summary:

This 510(k) submission contains information/data on modifications made to the submitter's own CLASS I device requiring 510(k). The following items are present and acceptable:

1. The name and 510(k) number of the SUBMITTER'S previously cleared device:

   CAMPYLOBACTER CHEK

   510(k) number: K173219

2. Submitter's statement that the **INDICATIONS FOR USE/INTENDED USE** of the modified device as described in its labeling **HAS NOT CHANGED** along with the proposed labeling which includes instructions for use, package labeling, and, if available, advertisements or promotional materials (labeling changes are permitted as long as they do not affect the intended use).

3. A description of the device **MODIFICATION(S)**, including clearly labeled diagrams, engineering drawings, photographs, user's and/or service manuals in sufficient detail to demonstrate that the **FUNDAMENTAL SCIENTIFIC TECHNOLOGY** of the modified device **has not changed. This change was for** an update to the Indications for Use to include detection of additional *Campylobacter* species.

4. Comparison Information (i.e., similarities and differences) to the submitter's legally marketed predicate device including, labeling, intended use, and physical characteristics.

Device & Predicate Device(s):	***CAMPYLOBACTER CHEK*** K191442 (Device)	***CAMPYLOBACTER CHEK*** K173219 (Predicate)
Similarities		
Intended Use/Indications for Use	The *CAMPYLOBACTER CHEK* test is an enzyme immunoassay for the qualitative detection of a *Campylobacter*-specific antigen in human fecal specimens. The *CAMPYLOBACTER CHEK* test is designed to detect *C. jejuni*, *C. coli*, *C. lari*, and *C. upsaliensis* from patients with 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.	The *CAMPYLOBACTER CHEK* test is an enzyme immunoassay for the qualitative detection of a *Campylobacter*-specific antigen in human fecal specimens. The *CAMPYLOBACTER CHEK* test is designed to detect *C. jejuni* and *C. coli* from patients with 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.
Measured Analyte	*Campylobacter*-specific antigen	Same
Target Population	Persons suspected of having *Campylobacter* infection	Same
Type of Test	Qualitative	Same
Sample Matrix	Human Fecal Specimen	Same
Controls	Positive and negative control included in the kit. Internal Control line	Same
Storage	Refrigerated (2-8ºC)	Same
Format	Microwell (96 tests)	Same
Technology	Enzyme Linked Immunoassay (ELISA)	Same
Interpretation	Spectrophotometrically and visually	Same
Specimen Type	Fecal specimens in Cary-Blair and C&S Transport Media	Same
Antibody Format	Monoclonal/Polyclonal	Same

Time to Result	Approximately 1 hour	Same
Differences		
Species Detected	*C. jejuni*, *C. coli*, *C. lari*, and *C. upsaliensis*	*C. jejuni* and *C. coli*

5. A Design Control Activities Summary which includes:

   a) Identification of Risk Analysis method(s) used to assess the impact of the modification on the device and its components, and the results of the analysis.

   A formal risk assessment was conducted for the *CAMPYLOBACTER CHEK* assay. This assessment included Failure Mode Effects and Analysis (FMEA) for the assay design. This analysis identified false negative and false positive results i.e., true *Campylobacter* infection not identified or false *Campylobacter* infection identified, as the worst-case risks to the patient. It was concluded based on FMEA and verification testing that the risks associated with detection of *C. lari* and *C. upsaliensis* are mitigated and therefore *CAMPYLOBACTER CHEK* is safe and effective for its intended use.

   b) Based on the Risk Analysis, an identification of the verification and/or validation activities required, including methods or tests used and acceptance criteria to be applied.

   The following studies were performed to demonstrate risk mitigation:

   Limit of Detection
   The limit of detection (LoD) for the modified *CAMPYLOBACTER CHEK* test was determined by spectrophotometry at both single (450 nm) and dual wavelength (450/620 nm) using whole organisms of both *C. lari* and *C. upsaliensis* spiked into unpreserved and preserved media, i.e., raw stool fecal matrix and Cary Blair and C&S media, respectively. 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. The LoDs that were determined using single wavelength readings for both species were equivalent to those obtained using dual wavelength readings. **Table 1** lists the LoD determined at dual wavelength.

Table 1. LoD for *C. lari* and *C. upsaliensis* Read at Dual Wavelength

C. lari		*C. upsaliensis*	
CFU/mL	CFU/test	CFU/mL	CFU/test
Fecal Matrix			
4.60×10^5	9,200	4.65×10^5	9,300
Cary Blair			
1.09×10^6	13,625	1.02×10^6	12,750
C&S			
1.18×10^6	14,750	1.02×10^6	12,750

Inclusivity Study

The sponsor tested the reactivity of *Campylobacter* isolates from Centre National de Reference des Campylobacters et Helicobacters - Centre Hospitalier Universitaire de Bordeaux by spiking each isolate listed in **Table 2** into negative fecal matrix at 2-3x LoD and testing with the *CAMPYLOBACTER CHEK*. All results were read at dual-wavelength and were positive, with the exception of *C. upsaliensis* strains 2016/1931 and 2017/0506H. *C. upsaliensis* strain 2016/1931 was positive at 4x LoD for all replicates and *C. upsaliensis* strain 2017/0506H was positive for a single replicate at 4x LoD and all replicates at 5x LoD.

Table 2. Strains Evaluated for Reactivity with Modified *CAMPYLOBACTER CHEK*

C. lari	*C. upsaliensis*
2013/0823H	2016/0385
2014/2772	2016/1931
2015/0519	2016/1950
2015/0814	2016/2697
2015/1582	2016/2826
2015/1657	2017/0349
2015/2189	2017/0506H
2015/2983	2017/2584
2016/0235	2018/0319H
2016/1130H	2018/1669

Interfering Substances Study

The modified *CAMPYLOBACTER 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 modified *CAMPYLOBACTER CHEK* test, except for vancomycin. One *C. upsaliensis* positive sample spiked with vancomycin unexpectedly yielded a negative result. However, upon repeat testing of the same aliquot, the sample tested positive in triplicate. This is acceptable.

Table 3. Interfering Substances

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 (1% 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)	Stearic Acid/Fecal Fat (40% w/v)
Tagamet (5 µg/mL)	TUMS (50 µg/mL)

Human Urine (5% v/v)	Vancomycin (0.25% w/v)

Prozone Effect Study
The purpose of this study was to demonstrate that a high concentration of *Campylobacter* (antigen) does not interfere with a positive reaction in the modified *CAMPYLOBACTER CHEK* test. High samples were prepared by spiking a negative fecal pool with $1.6x10^8$ whole organisms of *C. lari* and $1.28x10^8$ whole organisms of *C. upsaliensis*. A total of five different dilutions of *C. lari* and *C. upsaliensis* 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 of *Campylobacter*.

Analytical Validation Study
The performance of the modified *CAMPYLOBACTER CHEK* test was determined by testing a panel of five *C. lari* and five *C. upsaliensis* clinical isolates. All samples were prepared by spiking negative, pooled fecal matrix with whole organism at 2x LoD. Both unpreserved stool and preserved stool (Cary Blair and C&S transport media) were evaluated during the study. Due to availability of limited number of representative isolates, each isolate was tested once a day over a three-day period by multiple technicians at a single internal site for a total of 135 data points. The results of this study demonstrated positive percent agreement (PPA) with expected results of 100% for *C. lari* and 97.0% for *C. upsaliensis*. The results are illustrated in **Table 4**.

Table 4. Analytical Validation Study - Performance of the Modified *CAMPYLOBACTER CHEK*

Species	Percent Agreement	95% CI
C. lari	100% (135/135)	97.2%, 100%
C. upsaliensis	97.0% (131/135)	92.6%, 98.8%

The labeling for this modified subject device has been reviewed to verify that the indication/intended use for the device is unaffected by the modification. In addition, the submitter's description of the specific modification(s) and the comparative information between the modified and unmodified devices demonstrate that the fundamental scientific technology has not changed. The submitter has provided the design control information as specified in The New 510(k) Paradigm and on this basis, I recommend the device be determined substantially equivalent to the previously cleared predicate device.