510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY ONLY TEMPLATE

A. 510(k) Number:

K090700

B. Purpose for Submission:

To determine substantial equivalence for the ImmunoCard STAT! CAMPY, Model 7 used to detect Campylobacter (*C. jejuni* and *C. coli*) antigens in stool samples

C. Measurand:

Campylobacter jejuni and *Campylobacter coli* antigens

D. Type of Test:

Immunochromatographic rapid test based on the lateral flow principle

E. Applicant:

Meridian Bioscience, Inc.

F. Proprietary and Established Names:

ImmunoCard STAT! CAMPY, Model 7

G. Regulatory Information:

1. Regulation section: 21 CFR § 866.3110, Campylobacter spp.

2. Classification: Class I

3. Product code: LQP - Campylobacter spp.

4. Panel: Microbiology (83)

H. Intended Use:

1. Intended use:

   ImmunoCard STAT! CAMPY is an immunochromatographic rapid test for the qualitative detection of specific Campylobacter antigens in human stool.

ImmunoCard 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.

ImmunoCard STAT! CAMPY is not intended for point-of-care use. The device is intended for use in clinical hospital, reference, regional, private or state laboratory settings.

2. Indications for use:

   Same as Intended Use

3. Special conditions for use statement(s):

   For Prescription Use Only

4. Special instrument requirements:

   None

I. Device Description:

ImmunoCard STAT! Campy is a lateral flow-based immunoassay for the direct detection of Campylobacter antigen in stool. The assay uses monoclonal antibodies specific for an antigen common to *Campylobacter jejuni* and *Campylobacter coli*. Stool specimen is added to Sample Diluent buffer and the diluted sample is added to the sample port of the device. Campylobacter antigen in the diluted sample binds to the monoclonal antibody-colloidal gold conjugate as the sample moves through the device. The Campylobacter capture antibody bound to the assay membrane at the Test position of the device binds the antigen-Campylobacter specific antibody-colloidal gold complex and yields a visible pink-red line. The control line functions as the internal assay control by showing adequate flow of diluted sample through the test device; improper assay execution and/or deterioration of test reagents. The control line is a goat antimouse antibody bound at the Control position of the device. A visible pink-red line at the Control position should be present each time a sample or control is tested. If no pink-red control line is seen, the test is considered invalid.

Reagents and Test Components:

- ImmunoCard STAT! Campy Test Device: Plastic cassette containing a test strip with an immobilized monoclonal antibody specific to *Campylobacter jejuni* and *Campylobacter coli* in the Test Line and a goat anti-mouse antibody in the Control Line. The strip contains a gold-conjugated mouse monoclonal antibody specific to *C. jejuni* and *C. coli*, which serves as the detection antibody. The test device is provided in a sealed foil pouch with desiccant.

- ImmunoCard STAT! Campy Sample Diluent/Negative Control: A buffered protein solution containing sodium azide and gentamycin as preservatives

- ImmunoCard STAT! Campy Positive Control: Inactivated Campylobacter jejuni in a buffered protein solution containing sodium azide and gentamycin as preservatives

No calibrators are used with this device.

J. Substantial Equivalence Information:

1. Predicate device name(s):

   ProSpecT Campylobacter EIA and Premier™ CAMPY EIA

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

   K982315 and K083464, respectively

3. Comparison with predicates:

   Differences between the proposed device and the predicates are highlighted in bold font.

Item	ImmunoCard STAT!CAMPY	Predicate device ProSpecT Campylobacter	Predicate Device Premier CAMPY
Manufacturer	Meridian Bioscience	Remel	Meridian Bioscience
Assay type	Lateral flow	**EIA**	**EIA**
Intended use			
Qualitative/Quantitative	Qualitative	Qualitative	Qualitative
Screening, diagnostic or identification test	Diagnostic	Diagnostic	Diagnostic
Calibrator	No	No	No
Monitoring therapy	No	No	No
Reagents/components			
Microwells	No	**YES**	**YES**
Sample Diluent	Yes	Yes	Yes
Enzyme Conjugate	No	**YES**	**YES**
Wash Buffer	No	**YES**	**YES**
Substrate	No	**YES**	**YES**
Stop Solution	No	**YES**	**YES**
Positive Control	Yes	Yes	Yes
Negative Control	Yes	Yes	Yes
Test Device	Yes	**NO**	**NO**

Species detected				
C. coli		Yes		UNK	Yes
C. lari	No	No		No	
C. fetus	No	No		No	
Reading method				
Visual	Yes	Yes		Yes	
Spectrophotometric	No	**YES**		**YES**	
End point	Pos = visible pink-red line Neg = no line	**POS = YELLOW COLOR NEGATIVE = COLORLESS**		**POS = DEFINITE YELLOW COLOR NEG = COLORLESS VERY FAINT YELLOW**	
Calibrator	No	No		No	
Equipment	Not needed	**General laboratory semiautomated washer (optional) General laboratory spectrophotometer (optional)**		**General laboratory semiautomated washer (optional) General laboratory spectrophotometer (optional) StatFax microplate incubator/shaker (optional)**	
Antibody sources				
Capture	Mouse monoclonal	**Rabbit polyclonal**		Mouse monoclonal	
Detector	Mouse monoclonal	**Rabbit polyclonal**		Mouse monoclonal	
Sample Types				
Human stool (direct)	Yes	Yes		Yes	
Broth culture	No	**Yes**		No	
Endpoint determinations				
Visible?	Yes – pink-red line	Yes – **yellow color**		Yes – **yellow color**	
Positive (dual wavelength)	N/A	**Yes ≥ 0.140**		**Yes ≥ 0.100**	
Negative (dual wavelength)	N/A	**Yes < 0.100**		**Yes < 0.100**	
Indeterminant (dual wavelength)	N/A	**Yes 0.100 to 0.139**		**None**	

UNK = Unknown

K.   Standard/Guidance Document Referenced:

The sponsor provided Form FDA 3645 referencing the standard <u>User Protocol for Evaluation of Qualitative Test Performance</u> (FDA Recognition Number 020).

L. Test Principle:

ImmunoCard STAT! Campy is a lateral flow-based immunoassay for the direct detection of Campylobacter antigen in stool. ImmunoCard STAT! Campy assay uses monoclonal antibodies specific for an antigen common to Campylobacter jejuni and Campylobacter coli. Stool sample is added to Sample Diluent buffer using the transfer pipette provided with the kit. The diluted sample is added to the sample port of the device.

Campylobacter antigen in the diluted sample binds to the monoclonal antibody-colloidal gold conjugate as the sample moves through the device. The Campylobacter capture monoclonal antibody bound to the assay membrane at the Test position of the device central window binds antigen-Campylobacter-antibody-colloidal gold complex and yields a visible pink-red line. When no antigen is present, no complex is formed and no pink-red line will appear at the Test position of the device central window. The control line serves as the assay control by showing adequate flow of diluted sample through the test device, improper assay execution, and or deterioration of test reagents. The control line is a goat anti-mouse antibody bound at the Control position of the reading window. A visible pink-red line at the Control position of the device central window should be present each time a sample or control is tested. If no pink-red control line is seen, adequate sample flow has not occurred and the test is considered invalid.

M. Performance Characteristics (if/when applicable):

1. <u>Analytical performance:</u>

a. Precision/Reproducibility:

Intra-assay variability and inter-assay variability were assessed with a reference panel prepared from moderate positive (n = 2), negative (n = 2), high negative (n = 3) and low positive (n = 3) samples. High negative, low positive and moderate positive samples were prepared by inoculating negative stool matrix with known quantities of C. jejuni. In the case of low positive and high negative samples, the inoculum was added at concentrations that were at, or just below, the assay Limit of Detection (LoD). Aliquots of each panel were tested for five days, twice each day at three different test sites (Sites A, B and C). At least two technologists performed testing at each site.

Results for each site are tabulated below:

Sample ID	Sample Qual. Result	Site 1 data generated with kit lot 751530.001									
		Day 1 Run 1 DH	Day 1 Run 2 AML	Day 2 Run 1 DH	Day 2 Run 2 AML	Day 3 Run 1 DH	Day 3 Run 2 AML	Day 4 Run 1 DH	Day 4 Run 2 AML	Day 5 Run 1 DH	Day 5 Run 2 AML
Positive Control	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos
Negative Control	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg
Moderate Positive 1	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos
Moderate Positive 2		Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos
Low Positive 1	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos
Low Positive 2		Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos
Low Positive 3		Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos
High Negative 1	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg
High Negative 2		Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg
High Negative 3		Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg
Low Negative 1	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg
Low Negative 2		Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg
Percent Correlation		100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Correlation of cut off Specimens		100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%

Legend: DH etc = initials of person performing the test, Pos = positive, Neg = negative

Site 2 data generated with lot 751530.001

Sample ID	Sample Qual. Result	Day 1 Run 1 DM	Day 1 Run 2 JM	Day 2 Run 1 DM	Day 2 Run 2 JM	Day 3 Run 1 DM	Day 3 Run 2 JM	Day 4 Run 1 DM	Day 4 Run 2 JM	Day 5 Run 1 DM	Day 5 Run 2 JM
Positive Control	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos
Negative Control	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg
Moderate Positive 1	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos
Moderate Positive 2		Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos
Low Positive 1	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos
Low Positive 2		Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos
Low Positive 3		Pos	Pos	Pos	Neg	Pos	Pos	Pos	Pos	Pos	Pos
High Negative 1	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg
High Negative 2		Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg
High Negative 3		Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg
Low Negative 1	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg
Low Negative 2		Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg
Percent Correlation		100.0%	100.0%	100.0%	90.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Correlation of cut off Specimens		100.0%	100.0%	100.0%	83.3%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%

Legend: DH etc = initials of person performing the test, Pos = positive, Neg = negative

Site 3 data generated with lot 751530.001

Sample ID	Sample Qual. Result	Day 1 Run 1 KC	Day 1 Run 2 KMA	Day 2 Run 1 KC	Day 2 Run 2 KMA	Day 3 Run 1 KC	Day 3 Run 2 KMA	Day 4 Run 1 KC	Day 4 Run 2 KMA	Day 5 Run 1 KC	Day 5 Run 2 KMA
Positive Control	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos
Negative Control	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg
Moderate Positive 1	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos
Moderate Positive 2		Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos
Low Positive 1	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos
Low Positive 2		Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos
Low Positive 3		Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos
High Negative 1	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg
High Negative 2		Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg
High Negative 3		Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg
Low Negative 1	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg
Low Negative 2		Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg
Percent Correlation		100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Correlation of cut off Specimens		100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%

Legend: DH etc = initials of person performing the test, Pos = positive, Neg = negative

These results suggest that the ImmunoCard STAT! Campy assay is reproducible when used by different personnel within or between labs.

b.   *Linearity/assay reportable range:*

Not applicable – this is a qualitative test with no numerical output

c.   *Traceability, Stability, Expected values (controls, calibrators, or methods):*

Stability

A stability study was performed using a bracketed matrix representing the extreme conditions of storage. Studies were performed with preserved samples collected in Cary-Blair medium. The table below summarizes the study conditions:

No.	Sample Type	Sample Age	Storage Temp.	Storage Time	Case
1	Unpreserved	Fresh sample (0-48 hours old) Frozen sample (0-24 hours from thaw)	Refrigerated (2-8 C) for no more than 8 hours after collection If banked sample, test result immediately on thawing.	0-2 hours after preparation of preserved aliquot for test below	Baseline sample type. Baseline sample age. Baseline storage temperature. Baseline storage time.
2	Same as above	Same as above	Refrigerated (2-8 C)	Maximum 2-8 C storage time plus 24 hours 96 hours plus 24 hours (120 hours or 5 days)	Worst-case sample storage time for the baseline sample at the baseline temperature.
3	Same as above	Same as above	Upper limit of room temperature range + 2 C NT	Maximum room temperature storage time plus 24 hours NT	Worst-case sample storage time for the baseline sample at the worst-case limit of room temperature. Bracket not used in this study. No room temperature storage allowed.
4	Same as above	Same as above	Conventional freezer temperature (-16 to -28 C) Track temperature during use.	Conventional freezer storage time plus 24 hours 2 months plus 24 hours, verify 1 year (interim time point after 2 weeks plus 24 hours)	Worst-case frozen storage time for the baseline sample under conditions of conventional freezer storage.
5	Same as above	Same as above	Ultra low freezer temperature (-66 to -84 C) Track temperature during use.	Ultra low freezer storage time plus 24 hours 2 months plus 24 hours, verify 1 year (interim time point after 2 weeks plus 24 hours)	Best-case sample storage time for the baseline sample at the worst-case limit of ultra low freezer temperature.

The results showed no line for negative samples and a definite or weak line with positive samples. Positive samples, including low positive sample, remained positive in all cases. Negative samples, including high negative, remain negative in all cases. Sample suitability was maintained when diluted samples were stored for up to 24 hours at $20\text{-}25^0$C or $2\text{-}8^0$C. To ensure best practices, the sponsor recommends storage of diluted samples at $2\text{-}8\ ^0$C only.

d.	*Detection limit:*

Samples were prepared from negative, archival, unpreserved, semi-solid stool specimens. The negative status of the samples was confirmed by the predicate method. Samples were spiked with decreasing amounts C. *coli* or C. *jejuni* obtained from stocks prepared to MacFarland Standard 4. Inoculated samples were tested immediately. The concentration of organisms in each sample was as follows:

Organism C. *jejuni* Sample ID	Final organism concentration
Sample 1 - 2 dilutions below LoB	$1.5 \times 10"$
Sample 2 -1 dilution below LoB	$3.0 \times 10"$
Sample 3 -Target LoB	$6.0 \times 10"$
Sample 4 -1 dilution above LoB	1.2×10
Sample 5 -2 dilutions above LoB	$2.4 \times 10_1$

Organism C. *coli* Sample ID	Final organism concentration
Sample 1 - 2 dilutions below LoB	$3.75 \times 10"$
Sample 2 - 1 dilution below LoB	$7.50 \times 10°$
Sample 3 -Target LoB	1.50×10
Sample 4 -1 dilution above LoB	3.00×10
Sample 5 -2 dilutions above LoB	6.00×10

The assay LoB and LoD determined samples spiked with known levels of C. *coli* and C. *jejuni*. Values were the same for semi-solid, liquid/watery or solid stool samples as these samples are diluted prior to testing to deliver a uniform matrix to the test.

e.	*Analytical specificity:*

Interference Testing
In this study, the sponsor added selected drugs, and other non-microbial substances that might be present in stool samples from healthy persons or patients with signs and symptoms of gastroenteritis, to three positive and three negative samples. They then inoculated the samples with C. *jejuni* near the limit of detection (LoD) of the assay. The sponsor affirms that the following substances at the specified saturated solvent/diluent concentrations do not interfere with test results in the final concentrations listed: Barium sulfate (5 mg/mL); fecal fat (equivalent to 2.65 mg stearic plus 1.3 mg palmitic acids per mL), hemoglobin (as methemoglobin) (3.2 mg/mL), Imodium AD® (0.00667 mg/mL), Kaopectate® (0.87 mg/mL), mucin (3.33 mg/mL), Mylanta® (4.2 mg/mL), Pepto-

Bismol® (0.87 mg/mL), Prilosec® (0.5 mg/mL), Tagamet® (0.5 mg/mL), TUMS® (0.5 mg/mL), urine (5% v/v), whole blood (5% v/v).

Cross-reactivity Study

Crossreactivity studies were performed with positive and negative stool specimens inoculated with bacterial and fungal organisms to a final concentration of 1.1×10^8 CFU/mL and virus ranging from 1.3×10^4 to 3.1×10^6 TCID50/mL. None of the following organisms in stool reacted with Immuno*Card* STAT! CAMPY:

Aeromonas hydrophila, Bacteroides fragilis, Campylobacter fetus, Candida albicans, Citrobacter freundii, Clostridium difficile, Clostridium perfringens, Enterobacter cloacae, Enterococcus faecalis, Escherichia coli, Escherichia coli O157:H7, *Escherichia fergusonii, Escherichia hermannii, Helicobacter pylori, Klebsiella pneumoniae, Lactococcus lactis, Listeria monocytogenes, Peptostreptococcus anaerobius, Plesiomonas shigelloides, Proteus vulgaris, Pseudomonas aeruginosa, Pseudomonas fluorescens,* Salmonella Groups B-E, *Serratia marcescens, Shigella boydii, Shigella flexneri, Shigella sonnei, Staphylococcus aureus, Staphylococcus epidermidis, Vibrio parahaemolyticus, Yersinia enterocolitica,* Adenovirus Types 40 and 41, Coxsackievirus, Echovirus, and Rotavirus

Strain Reactivity Study

The sponsor tested the reactivity using various strains of *C. jejuni* and *C. coli* (as shown in the table below). Each strain was spiked into a negative stool matrix. The negative sample matrix was confirmed nonreactive with the predicate device. Strains were diluted in phosphate-buffered saline to a MacFarland Standard #4. Ten µL of each organism was spiked into 100 µL of stool matrix. The negative dilution control was prepared by spiking the matrix with buffer instead of organism. The negative dilution control was nonreactive when tested. Results showed that all strains were reactive.

Summary of Reactivity Study

Microorganism and ID #	Final conc. of microorganism in undiluted sample	Reactive? Y/N (at dilution)
C. jejuni		
12081	1.1×10^7 CFU/mL	Y
10940	1.1×10^7 CFU/mL	Y
38106	1.1×10^7 CFU/mL	Y
6951	1.1×10^7 CFU/mL	Y
29411	1.1×10^7 CFU/mL	Y
C. coli		
53138	1.1×10^8 CFU/mL	Y
36994	1.1×10^8 CFU/mL	Y
17755	1.1×10^8 CFU/mL	Y
10956	1.1×10^8 CFU/mL	Y

f. Assay cut-off:

Not Applicable

2. Comparison studies:

a. Method Comparison with Predicate:

See Clinical Studies Section

b. Matrix comparison:

Specimen matrix interference has not been observed in this assay as samples are significantly diluted before testing in Sample Diluent. For this reason, the Positive and Negative Controls supplied as part of this assay are prepared in matrices similar to the Sample Diluent. If control materials that are identical in composition to test samples are preferred, the user can prepare these by diluting known positive and negative specimens in Sample Diluent according to the SPECIMEN PREPARATION section of the package insert.

1. Clinical Studies:

a. Clinical Sensitivity

Immuno*Card* STAT! CAMPY was evaluated by three independent laboratories located in different geographical regions of the United States. Four hundred and twenty one qualified samples were tested. Of these samples 189 (45%) were retrospective frozen samples. Fifty one percent of the samples (216/421) were collected without a preservative. The remaining samples (205/421) were collected in a Cary-Blair medium. Samples were collected from males (44%) and females (52%). In the case of 4% of the patients, gender was not recorded. The age groups of the patients from whom samples were collected ranged from one month of age to 95 years. The sponsor compared the performance of their device to bacterial culture. No differences in test performance were observed based on patient age or gender.

Table 1. Performance characteristics by clinical site

Site	Positive Samples			Negative Samples		
	ICS/ Culture	Sensitivity %	95% CI	ICS/ Culture	Specificity %	95% CI
Site 1	17/17	100%	81.6-100%	92/95	96.8%	91.1-98.9%
Site 2	18/19	94.7%	75.4-99.1%	130/135	96.3%	91.6-98.4%
Site 3	17/17	100%	81.6-100%	131/138	94.9%	89.9-97.5%
Combined Sites	52/53	98.1%	90.1-99.7%	353/368	95.9%	93.4-97.5%

Table 2 – Performance characteristics by patient age

Patient Age	Positive Samples			Negative Samples		
	ICS/ Culture	Sensitivity %	95% CI	ICS/ Culture	Specificity %	95% CI
Birth to 1 month	0/0	N/A	N/A	1/1	100%	20.7-100%
> 1 month to 2 years	2/2	100%	34.2-100%	66/68	97.1%	89.9-99.2%
> 2 years to 12 years	5/5	100%	56.6-100%	88/93	94.6%	88.0-97.7%
> 12 years to 21 years	1/1	100%	20.7-100%	40/42	95.2%	84.2-98.7%
> 21 years	27/28	96.4%	82.3-99.4%	158/164	96.3%	92.2-98.3%
Not Defined	17/17	100%	81.6-100%	0/0	N/A	N/A

Table 3 – Performance characteristics by sample type (preserved vs unpreserved)

Specimen Type Preserved	Positive Samples			Negative Samples		
	ICS/ Culture	Sensitivity %	95% CI	ICS/ Culture	Specificity %	95% CI
Site 1	12/12	100%	75.8-100%	92/95	96.8%	91.1-98.9%
Site 2	13/14	92.9%	68.5-98.7%	61/66	92.4%	83.5-96.7%
Site 3	17/17	100%	81.6-100%	1/1	100%	20.7-100%
Specimen Type Unpreserved	ICS/ Culture	Sensitivity %	95% CI	ICS/ Culture	Specificity %	95% CI
Site 1	5/5	100%	56.6-100%	0/0	N/A	N/A
Site 2	5/5	100%	56.6-100%	69/69	100%	94.7-100%
Site 3	0/0	N/A	N/A	130/137	94.9%	89.8-97.5%

Table 4 – Performance characteristics of fresh and frozen samples

Specimen Type Fresh	Positive Samples			Negative Samples		
	ICS/ Culture	Sensitivity %	95% CI	ICS/ Culture	Specificity %	95% CI
Site 1	0/0	N/A	N/A	91/94	96.8%	91.0-98.9%
Site 2	2/3	66.7%	20.8-93.9%	130/135	96.3%	91.6-98.4%
Site 3	0/0	N/A	N/A	0/0	N/A	N/A
Total Fresh	2/3	66.7%	20.8-93.9%	221/229	96.5%	93.3-98.2%
Specimen Type Frozen	ICS/ Culture	Sensitivity %	95% CI	ICS/ Culture	Specificity %	95% CI
Site 1	17/17	100%	81.6-100%	1/1	100%	20.7-100%
Site 2	16/16	100%	80.6-100%	0/0	N/A	N/A
Site 3	17/17	100%	81.6-100%	131/138	94.9%	89.9-97.5%
Total Frozen	50/50	100%	92.9-100%	132/139	95.0%	90.0-97.5%

Site 1 – Prospective versus Retrospective Samples

Prospective samples (fresh)	ICS CAMPY			ProSpecT Campylobacter (predicate)			
Stool Culture	Positive	Negative	Total	Positive	Negative	Indeterm.	Total
Positive	0	0	0	0	0	0	0
Negative	3	91	94*	0	95	0	95
Total	3	91	94	0	95	0	95
Sensitivity	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Specificity	91/94	96.8%	91.0 – 98.9%	95/95	100%	96.1 – 100%	
Correlation	91/94	96.8%	91.0 – 98.9%	95/95	100%	96.1 – 100%	
Retrospective samples (frozen)	ICS CAMPY			ProSpecT Campylobacter (predicate)			
Stool Culture	Positive	Negative	Total	Positive	Negative	Indeterm.	Total
Positive	17	0	17	17	0	0	17
Negative	0	1	1	0	1	0	1
Total	17	1	18	17	1	0	18
Sensitivity	17/17	100%	81.6 – 100%	17/17	100%	81.6 – 100%	
Specificity	1/1	100%	20.7 – 100%	1/1	100%	20.7 – 100%	
Correlation	18/18	100%	82.4 – 100%	18/18	100%	82.4 – 100%	

Site 2 – Prospective versus Retrospective Samples

Prospective samples (fresh)	ICS CAMPY			ProSpecT Campylobacter (predicate)			
Stool Culture	Positive	Negative	Total	Positive	Negative	Indeterm.	Total
Positive	2	1	3	2	1	0	3
Negative	5	130	135	0	125	0	125*
Total	7	131	138	2	126	0	128
Sensitivity	2/3	66.7%	20.8 – 93.9%	2/3	66.7%	20.8 – 93.9%	
Specificity	130/135	96.3%	91.6 – 98.4%	125/125	100%	97.0 – 100%	
Correlation	132/138	95.7%	90.8 – 98.0%	127/128	99.2%	95.7 – 99.9%	
Retrospective samples (frozen)	ICS CAMPY			ProSpecT Campylobacter (predicate)			
Stool Culture	Positive	Negative	Total	Positive	Negative	Indeterm.	Total
Positive	16	0	16	16	0	0	16
Negative	0	0	0	0	0	0	0
Total	16	0	16	16	0	0	16
Sensitivity	16/16	100%	80.6 – 100%	16/16	100%	80.6 – 100%	
Specificity	N/A	N/A	N/A	N/A	N/A	N/A	
Correlation	16/16	100%	80.6 – 100%	16/16	100%	80.6 – 100%	

Site 3 – Prospective versus Retrospective Samples

Prospective samples (fresh)	ICS CAMPY			ProSpecT Campylobacter (predicate)			
Stool Culture	Positive	Negative	Total	Positive	Negative	Indeterm.	Total
Positive	0	0	0	0	0	0	0
Negative	0	0	0	0	0	0	0
Total	0	0	0	0	0	0	0
Sensitivity	N/A	N/A	N/A	N/A	N/A	N/A	
Specificity	N/A	N/A	N/A	N/A	N/A	N/A	
Correlation	N/A	N/A	N/A	N/A	N/A	N/A	
Retrospective samples (frozen)	ICS CAMPY			ProSpecT Campylobacter (predicate)			
Stool Culture	Positive	Negative	Total	Positive	Negative	Indeterm.	Total
Positive	17	0	17	17	0	0	17
Negative	7	131	138	1	137	0	138
Total	24	131	155	18	137	0	155
Sensitivity	17/17	100%	81.6 – 100%	17/17	100%	81.6 – 100%	
Specificity	131/138	94.9%	89.9 – 97.5%	137/138	99.3%	96.0 – 99.9%	
Correlation	148/155	95.5%	91.0 – 97.8%	154/155	99.4%	96.4 – 99.9%	

Combined Site Data- Prospective versus Retrospective Samples

Prospective samples (fresh)	ICS CAMPY			ProSpecT Campylobacter (predicate)			
Stool Culture	Positive	Negative	Total	Positive	Negative	Indeterm.	Total
Positive	2	1	3	2	1	0	3
Negative	8	221	229*	0	220	0	220**
Total	10	222	232	2	221	0	223
Sensitivity	2/3	66.7%	20.8 – 93.9%	2/3	66.7%	20.8 – 93.9%	
Specificity	221/229	96.5%	93.3 – 98.2%	220/220	100%	98.3 – 100%	
Correlation	223/232	96.1%%	92.8 – 97.9%	222/223	99.6%	97.5 – 100%	
Retrospective samples (frozen)	ICS CAMPY			ProSpecT Campylobacter (predicate)			
Stool Culture	Positive	Negative	Total	Positive	Negative	Indeterm.	Total
Positive	50	0	50	50	0	0	50
Negative	7	132	139	1	138	0	139
Total	57	132	189	51	138	0	189
Sensitivity	50/50	100%	92.9 – 100%	50/50	100%	92.9 – 100%	
Specificity	132/139	95.0%	90.0 – 97.5%^	138/139	99.3%	96.0 – 99.9%	
Correlation	182/189	96.3%	92.6 – 98.2%	188/189	99.5%	97.1 – 99.9%	

* One sample was QNS for testing by ICS CAMPY.

** Ten samples were excluded from the calculations due to a ProSpecT run control failure.

b. *Clinical Specificity*

   See 3a above

c. *Other Clinical Supportive data*

   N/A

4. Clinical cut-off:

   N/A

5. Expected Values/Reference Range:

The performance of Immuno*Card* STAT! CAMPY was evaluated during 2009 using retrospective positive and negative samples collected during 2008 and prospective positive and negative samples, which were collected in 2009. The samples were collected from different geographic regions in the United States. The incidence of positive samples was approximately 1.5% during the 2008 and approximately 1.2% during the 2009 sample collection seasons. The incidence for an individual laboratory may differ from this number since it is dependent on factors such as locale, the time of year and occurrence of an outbreak (if applicable).

N. Proposed Labeling:

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

O. Conclusion:

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