This Procedural Bulletin is intended to provide a ready outline reference for performance of the assay. These abbreviated directions for use are not intended to replace the complete package insert. It is the obligation of every manufacturer of medical devices labeled FOR *IN VITRO* DIAGNOSTIC USE to provide a complete package insert in accordance with FDA labeling regulation (21 CFR 809.10).

Quidel Corporation provides CLSI procedures for your use. The procedures are required to include the same information as listed in the package insert. Any modifications to this document are the sole responsibility of the Laboratory.

QuickVue TLI Campylobacter

CLIA Complexity: Moderate

For *in vitro* diagnostic use. IVD Rx ONLY

For Canadian Users: For Laboratory Use Only

A symbols glossary can be found at quidel.com/glossary.

INTENDED USE

The QuickVue TLI Campylobacter Test is a rapid membrane enzyme-linked immunosorbent assay for the qualitative detection of a *Campylobacter*-specific antigen in human fecal specimens. The QuickVue TLI Campylobacter Test is designed to detect *C. jejuni* and *C. coli, C. lari* and *C. upsaliensis* 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. **Caution: U.S. Federal Law restricts this device to sale by or on the order of a physician.**

EXPLANATION

Worldwide, *Campylobacter* species are the most common cause of bacterial gastroenteritis, with 400-500 million cases of diarrhea each year.[1] Infants in developing countries are at even greater risk, as are travelers to those countries.[2] *Campylobacter*–associated gastroenteritis is estimated to affect nearly 1 million people a year in the USA.[3] In approximately 1 of 1000 cases, *Campylobacter jejuni* is closely linked to the subsequent development of Guillian-Barre Syndrome, an acute auto-immune paralysis.[4] *C. jejuni* infection has also been associated with reactive arthritis in both children and adults.[4,5] 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.[4]

For *Campylobacter*, the current standard for identification is bacterial culture followed by microscopic examination of the organisms.[6] 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.[7,8] Thus, during transport or storage of specimens under aerobic conditions, the number of viable organisms can decrease, leading to potentially inaccurate culture results.[9] 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 QuickVue TLI Campylobacter Test allows detection of *Campylobacter jejuni* and *Campylobacter coli*, the species most commonly associated with human disease, in less than 30 minutes. Furthermore, the QuickVue TLI Campylobacter Test does not rely on bacterial viability, and can be performed on the bench-top with samples that have been exposed to air.

PRINCIPLE OF THE TEST

The QuickVue TLI Campylobacter 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	MEM DEV
Conjugate (2.5 mL) – Antibody to a *Campylobacter*-specific antigen coupled to horseradish peroxidase in a buffered protein solution (contains 0.05% ProClin® 300)*	CONJ ENZ
Diluent (22 mL) – Buffered protein solution with graduated dropper assembly (contains 0.05% ProClin® 300)*	DIL SPE
Positive Control (2 mL) – *Campylobacter*-specific antigen in a buffered protein solution (contains 0.05% ProClin® 300)*	CONTROL +
Substrate (3.5 mL) – Solution containing tetramethylbenzidine	SUBS REAG
Wash Buffer (12 mL) – Buffered solution with graduated dropper assembly (contains 0.05% ProClin® 300)*	WASH REAG
Disposable plastic transfer pipettes – Graduated at 25 µL, 100 µL, 200 µL, 300 µL, 400 µL and 500 µL	

*(contains 0.05% ProClin® 300)
Signal Word: Warning

H317: May cause an allergic skin reaction
P261, P272, P280, P302, P352, P333, P313, P321, P362, P364, P501

MATERIALS AND EQUIPMENT REQUIRED BUT NOT PROVIDED

- Small test tubes (e.g., plastic Eppendorf tubes)
- Vortex mixer
- Applicator sticks
- Pipettor and tips
- Timer
- Disposable gloves for handling fecal samples

SHELF LIFE AND STORAGE

The expiration date of the kit is given on the kit label. Expiration dates for each component are listed on the individual labels. The kit should be stored between 2°C and 8°C and returned promptly to the intended storage condition after use.

PRECAUTIONS

1. Rx Only – Prescription Only
2. Reagents from different kits should not be mixed or interchanged. Do not use a kit or component past the expiration date.
3. Each component in the kit should be inspected for any signs of leakage. Upon arrival, inspect the kit to ensure that components are not frozen or warm to the touch due to improper shipping conditions.
4. Inspect foil pouch before opening to ensure no holes are present and that it is sealed properly.
5. Bring all components to ROOM TEMPERATURE BEFORE USE!
6. Caps, tips and dropper assemblies are color-coded; do NOT mix or interchange!
7. Do not freeze the reagents. The kit should be stored between 2°C and 8°C.
8. The pouch containing the *Membrane Device* should be at room temperature before opening. Keep the membrane devices dry before use.
9. Hold reagent bottles vertically when dispensing reagents to ensure consistent drop size and correct volume.
10. Specimens and membrane devices should be handled and disposed of as potential biohazards after use. Do not place in trash. Wear disposable gloves when doing the test.
11. *Membrane Devices* cannot be reused.
12. The test has been optimized for sensitivity and specificity. Alterations of the specified procedure and/or test conditions may affect the sensitivity and specificity of the test. Do not deviate from the specified procedure.
13. Be attentive to the total assay time when testing more than one fecal specimen. Add *Diluent* first, and then add the *Conjugate* to each tube of *Diluent*. Then add specimen to the tube of Diluent/Conjugate. Thoroughly mix all of the diluted specimens, and transfer to the *Membrane Device*. The 15-minute incubation step begins after the last diluted sample-conjugate mixture has been transferred to the final *Membrane Device*.
14. If the *Substrate* reagent changes to a dark blue/violet color call technical services for replacement.
15. Fecal specimens may contain potentially infectious agents and should be handled at "Biosafety Level 2" as recommended in the CDC/NIH Manual "Biosafety in Microbiological and Biomedical Laboratories."
16. Reagents contain 0.05% ProClin® 300 as a preservative. Although the concentration is low, ProClin® 300 is known to be harmful. If skin irritation or rash occurs, get medical advice/attention. Take off contaminated clothing and wash it before reuse. Handle reagents according to existing regulations for laboratory safety and good laboratory practice.
17. Follow your national, regional, and local ordinances accordingly for waste disposal regulations. Do not place in trash, dispose of as hazardous waste.
18. For additional information on hazard symbols, safety, handling and disposal of the components within this kit, please refer to the Safety Data Sheet (SDS) available from Technical Support at technicalsupport@quidel.com.

COLLECTION, HANDLING, AND STORAGE OF FECAL SPECIMENS

Acceptable Sample Type	Do Not Use
Fresh Fecal Specimens	Fecal specimens in Formalin-based fixative (e.g., sodium acetate formalin, 10% formalin, merthiolate formalin)
Specimens in Transport Media (Cary Blair, C&S)	Fecal specimens in alcohol-based fixative (e.g., polyvinyl alcohol)
Frozen Fecal Specimens	Concentrated Fecal Specimens

Storage Condition	Recommended Storage Time
Fresh Samples stored between 2°C and 8°C	96 hours
Samples stored in Cary Blair media between 20°C and 30°C	96 hours
Samples stored in C&S media between 20°C and 30°C	96 hours

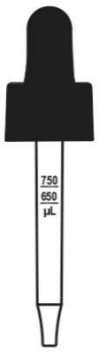
1. Standard collection and handling procedures used in-house for fecal specimens are appropriate. Fresh fecal specimens should be collected in clean, leak-proof containers, stored between 2° and 8°C, and tested within 96 hours of collection. Specimens that cannot be tested within this time should be stored at ≤ 10°C. Fecal specimens that are stored frozen may be thawed up to 5 times. If using frozen specimens, thaw at room temperature.
2. Specimens in transport media may be stored for up to 96 hours between 20°C and 30°C.
3. Storing fecal specimens in the *Diluent* is NOT recommended.
4. Do not allow the fecal specimens to remain in the *Diluent/Conjugate* mixture for >30 minutes.

SPECIMEN PREPARATION

1. Bring all reagents, fecal specimens, and the required number of *Membrane Devices* to room temperature before use. It is recommended to remove the reagents from the foam insert to reduce the time needed to warm to room temperature.

2. Set up and label one small test tube for each specimen, and optional external controls as necessary.

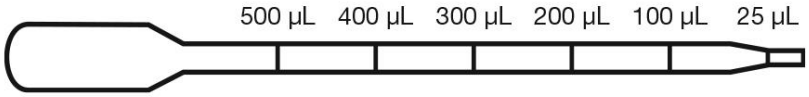
3. **For unpreserved fecal specimens, using the black graduated dropper assembly, add 750 µL (2nd graduation from the tip) *Diluent* to each tube. For specimens in Cary Blair or C&S transport media, add 650 µL (1st graduation from the tip) of *Diluent* to each tube.**



Sample Type	Volume of *Diluent*
Fresh or Frozen Fecal Specimens	750 µL (2nd graduation from tip)
Specimens in transport media (Cary Blair, C&S)	650 µL (1st graduation from tip)
External Controls (positive and negative)	750 µL (2nd graduation from tip)

4. Add one drop of *Conjugate* (red capped bottle) to each tube. Gently mix the *Conjugate* in the bottle by inverting several times prior to addition.

5. Obtain one disposable plastic transfer pipette (supplied with the kit) for each sample – the pipettes have raised graduations at 25 µL, 100 µL, 200 µL, 300 µL, 400 µL, and 500 µL.
   Graduated Transfer Pipette:



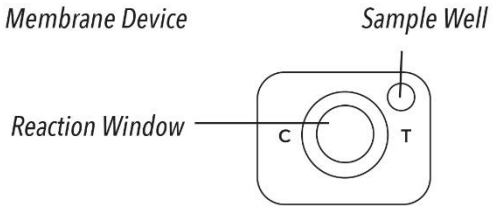
6. **Mix all specimens thoroughly regardless of consistency – it is essential that the specimens be evenly suspended before transferring**.
   Liquid/Semi-solid specimens – Pipette 25 µL of specimen with a transfer pipette and dispense into the *Diluent/ Conjugate* mixture. Use the same transfer pipette to mix the diluted specimen.

Formed/Solid specimens – Care must be taken to add the correct amount of formed feces to the sample mixture. Mix the specimen thoroughly using a wooden applicator stick and transfer a small portion (approximately 1 mm diameter, the equivalent of 25 µL) of the specimen into the *Diluent/Conjugate* mixture. Emulsify the specimen using the applicator stick.
Fecal specimens in Cary Blair or C&S transport media – Pipette 100 µL of sample into the *Diluent/Conjugate* mixture.
Note: Transferring too little specimen, or failure to mix and completely suspend the specimen in the *Diluent/Conjugate* mixture, may result in a false-negative test result. The addition of too much fecal specimen may cause invalid results or restricted sample flow.

7. **Optional External Control Samples:**
   Optional control devices may be run concurrently with patient samples.
   External Positive Control – add one drop of *Positive Control* (gray-capped bottle) into the *Diluent/Conjugate* mixture.
   External Negative Control – add 25 µL *Diluent* into the *Diluent/Conjugate* mixture.

TEST PROCEDURE

1. Obtain one *Membrane Device* per specimen, and one *Membrane Device* per optional external positive or negative control as necessary. The foil bags containing the devices should be brought to room temperature before opening. Use the device immediately after opening. Label each device appropriately and orient it on a flat surface so that the small *Sample Well* is located in the top right corner of the device.



2. Close each tube of diluted specimen and mix thoroughly. Proper mixing can be achieved by vortexing the tube for 5-20 seconds. Once a patient sample, or *Positive Control,* has been diluted in the *Diluent/Conjugate* mixture, it may be incubated at room temperature for up to 30 minutes prior to addition to the *Membrane Device.*

3. Make sure that each diluted sample is thoroughly mixed before adding to the *Membrane Device*. **Using a new transfer pipette**, transfer 500 µL (topmost graduation) of the diluted sample-conjugate mixture into the ***Sample Well*** of a *Membrane Device*. When adding the sample into the Sample Well, make sure that the tip of the transfer pipette is inside the Sample Well and angled towards the *Reaction Window*, making certain to expel the liquid sample onto the wicking pad inside the *Membrane Device*.

4. Incubate the device at room temperature for 15 minutes – the sample will wick through the device and a wet area will spread across the *Reaction Window*.
   NOTE FOR SAMPLES THAT FAIL TO MIGRATE:
   Occasionally, a diluted sample fails to migrate properly and the Reaction Window does not fully wet. If the Reaction Window does not appear to be completely wet within 5 minutes of adding the sample to the Sample Well, then add 100 µL (4 drops) of Diluent to the Sample Well and wait an additional 5 minutes (for a total of 20 minutes).

5. After the incubation, add 300 µL of *Wash Buffer* to the ***Reaction Window*** using the graduated white dropper assembly. Allow the *Wash Buffer* to flow through the *Reaction Window* membrane and be absorbed completely.

6. Add 2 drops of *Substrate* (white-capped bottle) to the ***Reaction Window***. Read and record results visually after 10 minutes.

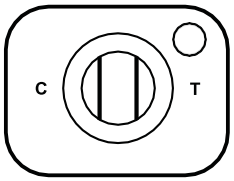
INTERPRETATION OF RESULTS

1. Interpretation of the test is most reliable when the device is read at the end of the 10-minute reaction period. Read the device at a normal working distance in a well-lit area. View with a line of vision directly over the device.

2. Observe device for the appearance of a vertical blue line on the "C" side (Control) of the *Reaction Window*, representing the internal positive control line. The appearance of any blue control line represents a valid internal control. The background may appear white to light blue in color. Observe device for the appearance of a blue line on the "T" side (Test) of the *Reaction Window* representing the test line. The line may appear faint to dark in intensity.

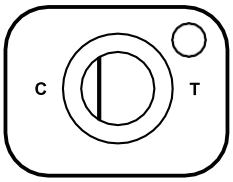
Positive Result

A positive result may be interpreted at any time between the addition of *Substrate* and the 10-minute read time. For a positive result, the blue "T" (Test) line and the blue "C" (Control) line are visible. The lines may appear faint to dark in intensity. An obvious partial line is interpreted as a positive result. Do not interpret membrane discoloration as a positive result. A positive result indicates the presence of a *Campylobacter*-specific antigen.



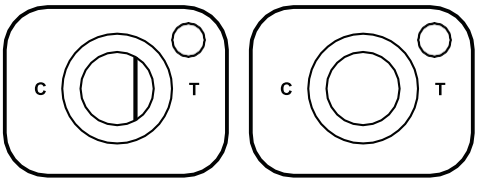
Negative Result

A test cannot be interpreted as negative or invalid until 10 minutes following the addition of *Substrate*. A single vertical blue line is visible on the left side of the *Reaction Window*, beside the "C" and no test line is visible on the "T" side of the *Reaction Window*. A negative result in the test portion indicates a *Campylobacter*-specific antigen is either absent from the specimen or is present at a concentration below the detection limit of the test.



Invalid Result

The test result is invalid if a blue line is not present beside the "C" at the completion of the reaction period.



QUALITY CONTROL

Internal

A vertical blue line must be visible on the left side of the *Reaction Window*, beside the "C" (Control) on every *Membrane Device* that is tested. The appearance of the blue control line confirms that the sample and reagents were added correctly, that 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. A uniform background in the result area is considered an internal negative control.

External

The reactivity of the QuickVue TLI Campylobacter Test should be verified upon receipt using the *Positive Control* and negative control (*Diluent*). The *Positive Control* is supplied with the kit (gray-capped bottle). The

Positive Control confirms the reactivity of the other reagents associated with the assay, and is not intended to ensure precision at the analytical assay cut-off. *Diluent* is used for the negative control. Additional tests can be performed with the controls to meet the requirements of Local, State and/or Federal regulations and/or accrediting organizations.

LIMITATIONS

1. The QuickVue TLI Campylobacter Test is used to detect a *Campylobacter*-specific antigen in human fecal specimens. The test confirms the presence of antigen in feces and this information should be taken under consideration by the physician in light of the clinical history and physical examination of the patient.
2. Optimal results with the QuickVue TLI Campylobacter 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.
3. Some specimens may give weak reactions. This may be due to a number of factors such as the presence of low levels of antigen, the presence of binding substances, or inactivating enzymes in the feces. The lines may consequently appear faint to dark in intensity. These specimens should be reported as positive if any blue line, even a partial line, is observed.
4. Transferring too little specimen, or failure to mix and completely suspend the specimen in the *Diluent/ Conjugate* mixture, may result in a false-negative test result. The addition of too much fecal specimen may cause invalid results or restricted sample flow.
5. Fecal specimens preserved in 10% Formalin, merthiolate formalin, sodium acetate formalin, or polyvinyl alcohol cannot be used.
6. The QuickVue TLI Campylobacter Test is qualitative. The intensity of the color should not be interpreted quantitatively.
7. No data exists on the effects of colonic washes, barium enemas, laxatives, or bowel preparations on the performance of the QuickVue TLI Campylobacter Test. All of these procedures can result in extensive dilution or the presence of additives that may affect test performance.
8. Negative results should not definitively rule-out the presence of *Campylobacter* species in suspected patients. Levels of organism may be present in feces beneath the limit of detection for the QuickVue TLI Campylobacter Test, and therefore, if *Campylobacter* is suspected, alternative testing should be conducted.

EXPECTED VALUES

The QuickVue TLI Campylobacter Test detects the presence of a *Campylobacter*-specific antigen in human fecal specimens. Expected values for a particular population should be established by each laboratory, and will vary depending on local food safety practices, sanitation of water sources, country, and season of year.[10] FoodNet, the U.S. Food-Borne Diseases Active Surveillance Network, reported an annual incidence of 13.45 per 100,000 population for *Campylobacter* infection between 1996 to 2012.[11] Globally, incidence rates can reach >400 per 100,000.[12,13] Reported annual incidence rates in fecal samples submitted for testing range from 1-2%.[14,15] Higher incidence rates (up to 7%) are seen in the summer months and in preschool-aged children.[10,15]

PERFORMANCE CHARACTERISTICS

Prospective Study

The performance of the QuickVue TLI Campylobacter Test was evaluated at 4 independent sites. Prospective incoming fecal specimens were collected and tested by culture and the QuickVue TLI Campylobacter Test. The following table shows a summary of the clinical performance of the QuickVue TLI Campylobacter Test for all 4 sites combined. The results of the study show that the QuickVue TLI Campylobacter 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.

QuickVue TLI Campylobacter Test versus Culture

N = 1552	Culture Positive	Culture Negative
QuickVue TLI Campylobacter Test Positive	34	13*
QuickVue TLI Campylobacter Test 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, Inc. 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 QuickVue TLI Campylobacter Test positive were confirmed to be positive for *C. jejuni* with all test methods.

Two of the 13 specimens that were culture negative and QuickVue TLI Campylobacter 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 QuickVue TLI Campylobacter 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 QuickVue TLI Campylobacter 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 QuickVue TLI Campylobacter 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 QuickVue TLI Campylobacter Test. All 30 specimens tested positive for *Campylobacter* spp. by all methods, yielding 100% correlation with all test methods.

REPRODUCIBILITY
The reproducibility of the QuickVue TLI Campylobacter Test was determined using 8 human fecal samples coded to prevent their identification during testing. Testing was performed at 2 independent laboratories and on-site at TECHLAB, Inc. The samples were tested twice a day over a 5-day period by multiple technicians at each site using 2 different kit lots. Positive and negative controls were 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.

CROSS-REACTIVITY

The QuickVue TLI Campylobacter 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 QuickVue TLI Campylobacter Test.

Acinetobacter baumannii
Aeromonas hyrophila
Bacillus cereus
Bacillus subtilis
Bacteroides fragilis
Campylobacter concisus
Campylobacter fetus
Campylobacter hyointestinalis
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 0157:H7 (non-toxigenic)
Escherichia coli 0157:H7 (toxigenic)
Escherichia fergusonii
Escherichia hermanii
Helicobacter pylori
Kiebsiella 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
Coxsackievirus B2,B3,B4,B5
Echovirus 9,11,18,22,33
Enterovirus 68,69,70,71
Human Coronavirus
Human Rotavirus
Norovirus

Campylobacter species that were shown to be reactive with the QuickVue TLI Campylobacter Test. *C. helveticus* (strain 54661) was found to be positive at 3.08 x 10^6 CFU/mL (4 x LoD of *C. coli*).

INCLUSIVITY STUDY

The specificity of the QuickVue TLI Campylobacter Test was evaluated using several strains of *Campylobacter jejuni*, *Campylobacter coli, Campylobacter lari* and *Campylobacter upsaliensis.* 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

C. lari strains: 2013/0823H, 2014/2772, 2015/0519, 2015/0814, 2015/1582, 2015/1657, 2015/2189, 2015/2983, 2016/0235, 2016/1130H

C. upsaliensis strains: 2016/0385, 2016/1931, 2016/1950, 2016/2697, 2016/2826, 2017/0349, 2017/0506H, 2017/2584, 2018/0319H, 2018/1669

C. lari and *C. upsaliensis* strains were obtained from Centre National de Reference des Campylobacters et Helicobacters - Centre Hospitalier Universitaire de Bordeaux.

INTERFERING SUBSTANCES (U.S. FORMULATION)

The following substances had no effect on positive or negative QuickVue TLI Campylobacter 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 (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), 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).

ANALYTICAL SENSITIVITY

The analytical sensitivity of the test was determined by using *C. jejuni, C. coli, C. lari,* and *C. upsaliensis* whole organism culture preparations in a sample matrix. The concentration of *C. jejuni*, *C. coli, C. lari,* and *C. upsaliensis* organisms in fecal matrix at which specimens are positive by the QuickVue TLI Campylobacter Test 95% of the time is the assay limit-of-detection (LoD).

The Limit of Detection (LoD) for the QuickVue TLI Campylobacter Test with raw fecal sample 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 QuickVue TLI Campylobacter Test with raw fecal sample 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*.

The Limit of Detection (LoD) for the QuickVue TLI Campylobacter Test with raw fecal sample was established at 1.23×10^6 CFU/mL (18636 CFU/test) for *C. lari*. For specimens in Protocol™ Cary Blair media, the LoD was established at 3.54×10^6 CFU/mL (55313 CFU/test) for *C. lari*. For specimens in Protocol™ C&S media, the LoD was established at 2.27×10^6 CFU/mL (35469 CFU/test) for *C. lari*.

The Limit of Detection (LoD) for the QuickVue TLI Campylobacter Test with raw fecal sample was established at 2.68×10^6 CFU/mL (40606 CFU/test) for *C. upsaliensis*. For specimens in Protocol™ Cary Blair media, the LoD was established at 2.43×10^6 CFU/mL (37969 CFU/test) for *C. upsaliensis*. For specimens in Protocol™ C&S media, the LoD was established at 5.04×10^6 CFU/mL (78750 CFU/test) for *C. upsaliensis*.

PROZONE

To ensure that a high concentration of *Campylobacter* antigen does not interfere with a positive reaction in the QuickVue TLI Campylobacter 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.

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ASSISTANCE

If you have any questions regarding the use of this product, please contact Quidel Technical Support at 1.800.874.1517 (in the U.S.) or technicalsupport@quidel.com. If outside the U.S., further information can be obtained from your distributor, or directly from Quidel at one of the numbers listed below. Reference **quidel.com** to see more options for Support.

Country	Phone	E Mail Address
Europe, Middle East and Africa	+353 (91) 412 474 (main) 0 1800 200441 (toll free)	emeatechnicalsupport@quidel.com
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Germany	+49 (0) 7154 1593912	
Netherlands	0 800 0224198	
Switzerland	0 800 554864	
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China	0400 920 9366 or +86 021 3217 8300	chinatechnicalservice@quidel.com

CL91-344-01_EN_C (01/20)

Test Procedure Approval and Review Sheet

Prepared By:	
Date:	
Supervisor Review:	
Date:	
Laboratory Director or Designee Approval:	
Implementation Date:	
Supersedes Procedure Dated:	
Date Procedure Retired:	

Laboratory Director or Designee	Date Reviewed	Laboratory Director or Designee	Date Reviewed

QuickVue TLI Campylobacter Test Verification Form

Account Name: _____

Address: _____

_____

Telephone: _____

QuickVue TLI
Campylobacter Lot #/Exp: _____

Date: _____

Supervisor Signature: _____

Record the results from reference samples below.

Record the Sample #, the expected results, the **QuickVue TLI Campylobacter Test** results, Tester's Initials, and any comments. After the **QuickVue TLI Campylobacter Test** results have been recorded (positive or negative) then record the Expected Results (positive or negative).

Sample #	Expected Results	**QuickVue TLI Campylobacter Test** Results	Tester's Initials	Comments

QuickVue TLI Campylobacter Verification Form (continued)

Sample #	Expected Results	**QuickVue TLI Campylobacter Test** Results	Tester's Initials	Comments

Review: _____ Date: _____

Laboratory Director Review and Approval for Clinical Use: _____

Date: _____

QuickVue TLI Campylobacter Test External Quality Control

There are two options for complying with CLIA's daily QC requirements for non-waived test systems under Section 493.1256 of the regulations:

- *Run two levels of external controls daily before patient testing OR*
- *Laboratories may develop and implement an IQCP for each non-waived test system.*

Quidel IQCP Support Documents may obtained upon request. The following listed conditions are also required as a minimum requirement:

External QC testing is recommended:

- When a new shipment of kits is received
- Additional tests can be performed with the controls to meet the requirements of local, state, and/or federal regulation and/or accrediting organizations

Date	**QuickVue TLI Campylobacter Test** Kit Lot/Exp	Positive Ctrl Lot/Exp	Negative Ctrl (Diluent) Lot/Exp	Positive Control Result	Negative Control Result	Tester's Initials	Comments

Reviewed by: _____ Date: _____

QuickVue TLI Campylobacter Test Internal Control Results and Patient Record

Lot Number _____ **Exp. Date** _____

Record the Date, Patient's Name, Patient Test Result, Internal Control Results and the Tester's initials.

Positive Internal Control = A vertical blue line must be visible on the left side of the *Reaction Window*, beside the "C" (Control) on every *Membrane Device* that is tested.

Negative Internal Control = A uniform background in the result area.

Date	Patient Name	Patient ID Number	Patient Results	Internal Control Result		Internal Controls		Comments	Tester's Initials
			Positive or Negative	**Invalid**	**Valid**	**+**	**–**		

Reviewed by: _____Date: _____

QuickVue TLI Campylobacter Test Lot to Lot Comparisons

Name of Facility: _____

External Quality Controls are required to test a new lot of reagents.

- When a new shipment or new lot of kit is received
- When required by local, state, and/or federal regulations, accrediting groups, or your lab's Quality Control procedures

	CURRENT QuickVue TLI Campylobacter Test In-Use Kit					**NEW QuickVue TLI Campylobacter Test Kit**					
Date	**QuickVue TLI Campylobacter Test** Kit Lot/Exp	Pos Control Lot/Exp	Neg Control Lot/Exp	Pos Control Result	Neg Control Result	**QuickVue TLI Campylobacter Test** Kit Lot/Exp	Pos Control Lot/Exp	Neg Control Lot/Exp	Pos Control Result	Neg Result	Tech's Initials

Reviewed by: _____ Date: _____

Quality Assessment Review Form and Checklist

These forms are used for periodical review of the patient testing process. These should be filed with the quality assessment records.

Quality Assessment Activity	Comments	Date	Initials
Patient Test Management: Evaluate criteria for specimen submission, handling, and rejection; test results requisitions and reporting, accuracy and reliability of reports.			
Quality Control: Assess control data, errors in reporting results, and corrective actions taken with appropriate documentation records.			
Proficiency Testing: Review the effectiveness of corrective actions taken for unsatisfactory performance or failures.			
Comparison of Test Results: Review at least semi-annually comparative results for multiple methods, instruments, or site correlations when more than one procedure exists.			
Relationship of Patient Test Information to Test Results*:* Evaluate patient test reports for accuracy of patient information, test results, and normal ranges. Identify and evaluate results inconsistent with Patient's age, sex, diagnosis, and other test parameters.			
Personnel: Evaluate the effectiveness of policies and procedures for assuring employees' competence of testing and reporting test results.			
Communications: Evaluate documented problems and corrective actions that occur between the laboratory and the authorized individual who orders or receives the test result.			
Complaint Investigation: Evaluate documented complaints and corrective actions.			
Quality Assessment Reviews with Staff: Document discussion with Staff regarding identified problems and corrective actions during the QA review.			

Temperature Log

Equipment: _____

Name of Facility: _____

To be recorded at the beginning of each workday. Temperature Range: _____

Date	˚C	Initials	Adjustments	Date	˚C	Initials	Adjustments