

TRAINING UPDATE

Lab Location: SGMC & WAH
Department: Core

Date Distributed: 10/6/2015
Due Date: 10/28/2015
Implementation: 10/28/2015

DESCRIPTION OF PROCEDURE REVISION

Name of procedure:

C Diff Quik Chek Complete SGAH.M34, WAH.M32 v2

Description of change(s):

Minor changes

Section	Reason
2	Added sentence to principle to be consistent with Package Insert
3.1	Added special collection information about specimens containing barium, laxatives, enemas, bowel preps or colonic washes.
3.2	Removed Cary-Blair transport as acceptable specimen
4.1, 14.4, 17	Changed manufacturer's name from Wampole to TechLab
4.2	Added note about substrate
8.1	Added detail regarding the need to hold dropper bottles vertically.
8.1	Removed instruction for Cary-Blair transport
13, 14	Moved some information from Limitations to Procedure Notes to be consistent with BPT SOP. Added caution about colonic washes, barium enemas, laxatives, and bowel preps.

This revised SOP will be implemented on October 28, 2015

Document your compliance with this training update by taking the quiz in the MTS system.

Approved draft for training (version 2)

Technical SOP

Title	C. DIFF QUIK CHEK COMPLETE™	
Prepared by	Ron Master	Date: 07/18/2010
Owner	Ron Master	Date: 07/18/2010

Laboratory Approval		Local Effective Date:
Print Name and Title	Signature	Date
<i>Refer to the electronic signature page for approval and approval dates.</i>		

Review		
Print Name	Signature	Date

TABLE OF CONTENTS

1. Test Information..... 2

2. Analytical Principle 3

3. Specimen Requirements..... 3

4. Reagents 4

5. Calibrators/Standards 6

6. Quality Control 6

7. Equipment And Supplies 8

8. Procedure 8

9. Calculations..... 10

10. Reporting Results And Repeat Criteria..... 10

11. Expected Values..... 12

12. Clinical Significance..... 13

13. Procedure Notes 13

14. Limitations Of Method 14

15. Safety 14

16. Related Documents 15

17. References..... 15

18. Revision History 15

19. Addenda 16

1. TEST INFORMATION

Assay	Method/Instrument	Local Code
GDH and <i>C. difficile</i> toxin A&B	Manual, Rapid membrane EIA	QCDIF

Synonyms/Abbreviations
Antigen - GDH – glutamate dehydrogenase - <i>C. difficile</i> antigen, <i>C diff</i> antigen Toxin - <i>C. difficile</i> toxin A&B, <i>C diff</i> toxin

Department
Microbiology

Form revised 2/02/2007

2. ANALYTICAL PRINCIPLE

The Tech Lab® C. DIFF QUIK CHEK COMPLETE® TEST (distributed by Alere) is a rapid membrane enzyme immunoassay for simultaneous detection of *Clostridium difficile* glutamate dehydrogenase (GDH) antigen and toxins A and B in a single reaction well. The device contains a Reaction Window with three vertical lines of immobilized antibodies. The antigen test line (“Ag”) contains antibodies against *C. difficile* glutamate dehydrogenase. The control line (“C”) is a dotted line that contains anti-horseradish peroxidase (HRP) antibodies. The toxin A and B test line (“Tox”) contains antibodies against *C. difficile* toxins A and B. The conjugate consists of antibodies to glutamate dehydrogenase and antibodies to toxins A and B coupled to horseradish peroxidase. During the incubation period, any glutamate dehydrogenase and toxins A and B in the sample bind to the antibody-peroxidase conjugates. The antigen-antibody-conjugate complexes migrate through a filter pad to a membrane where they are captured by the immobilized glutamate dehydrogenase-specific and toxins A and B-specific antibodies in the lines. When both GDH and Toxin are detected in the sample, it is reported as positive for toxigenic *C. difficile*. When both GDH and Toxin are not detected in the sample, it is reported as negative for toxigenic *C. difficile*. All other samples are reflexed to PCR to determine the presence of toxigenic *C. difficile*.

3. SPECIMEN REQUIREMENTS

CAUTION: Pathogenic microorganisms, including hepatitis viruses and Human Immunodeficiency Virus may be present in clinical specimens. “Standard Precautions” and institutional guidelines should be followed in handling all items contaminated with blood and other body fluids.

3.1 Patient Preparation

Component	Special Notations
Fasting/Special Diets	Not Applicable
Specimen Collection and/or Timing	Not Applicable
Special Collection Procedures	Collect fresh stool in sterile, leak-proof container without media, preservative, or additive. Specimens containing barium, laxatives, enemas, bowel preps, or colonic washes are not acceptable.
Other	Submit specimen immediately to Laboratory or store refrigerated until sent.

3.2 Specimen Type & Handling

Criteria	
Type	-Preferred -Other Acceptable
	Non-formed raw stool (no preservative) None

Criteria	
Collection Container	Clean airtight container
Volume - Optimum - Minimum	N/A 2 mm diameter sized portion for solid stool 50 µl for liquid or semi-solid stool
Transport Container and Temperature	Same as above. Transport at room temperature.
Stability & Storage Requirements	Room Temperature: Not Recommended
	Refrigerated: Acceptable: 2-8°C for up to 72 hours
	Frozen: -20°C or colder if sample cannot be tested within 72 hours.
Timing Considerations	Ideally samples must be tested within 24 hours, otherwise the storage requirements above must be observed.
Unacceptable Specimens & Actions to Take	Stool samples in 10% Formalin, merthiolate formalin, sodium acetate formalin, or polyvinyl alcohol preservatives. Reject sample and request an unpreserved sample. Also reject the following: <ul style="list-style-type: none"> • Stools submitted in transport media or on a swab • Unfrozen stools greater than 72 hours old • Rectal swabs • Specimens containing barium
Compromising Physical Characteristics	N/A
Other Considerations	Store specimens frozen ($\leq -10^{\circ}\text{C}$) if the test cannot be performed within 72 hours of collection, but note that freezing and thawing of the specimen may result in loss of activity due to degradation of the toxins. If using frozen specimens, thaw at room temperature. A single freeze thaw cycle should not affect results. Repeated freezing and thawing of samples should be avoided. Storing fecal specimens in the <i>Diluent</i> is NOT recommended.

4. REAGENTS

Refer to the Material Safety Data Sheet (MSDS) supplied with the reagents for complete safety hazards. Refer to the section in this procedure covering “SAFETY” for additional information.

4.1 Reagent Summary

Reagents / Kits	Supplier & Catalog Number
TechLab C. DIFF QUIK CHEK COMPLETE™ Kit	Tech Lab (distributed through Alere) Catalog Numbers: 30525C 30550C

4.2 Reagent Preparation and Storage

NOTES: Date and initial all reagents upon opening. Each container must be labeled with (1) substance name, (2) lot number, (3) date of preparation, (4) expiration date, (5) initials of tech, (6) any special storage instructions; check for visible signs of degradation.

Refer to the Material Safety Data Sheet (MSDS) for a complete description of hazards. If a specific hazard is present, it will be noted in this procedure when the hazard is first encountered in a procedural step.

Storage Instructions: This product is ready for use and no further preparation is necessary. Store product in its original container at 2-8°C until used. Allow product to equilibrate to room temperature before use.

Kit Components	Container	Storage/ Stability	Preparation
Membrane Devices	Each pouch contains 1 device	Store at 2-8°C. Stable until expiration date on vial label.	Ready for use.
Diluent	22 mL per bottle	Store at 2-8°C. Stable until expiration date on vial label.	Ready for use.
Wash Buffer	12 mL per bottle	Store at 2-8°C. Stable until expiration date on vial label.	Ready for use.
Substrate	3.5 mL per bottle	Store at 2-8°C. Stable until expiration date on vial label. Note: If color changes to a dark blue/violet color contact the manufacturer's technical services for replacement.	Ready for use.
Conjugate	2.5 mL per bottle	Store at 2-8°C. Stable until expiration date on vial label.	Ready for use.
Positive Control	1 mL per bottle	Store at 2-8°C. Stable until expiration date on vial label.	Ready for use.
Disposable plastic transfer pipettes	50 per kit	N/A	N/A

Warnings and Precautions:

1. Reagents from different kits should not be mixed or interchanged. Do not use a kit past the expiration date.
2. Bring all components to ROOM TEMPERATURE BEFORE USE.
3. Caps, tips and dropper assemblies are color-coded; do NOT mix or interchange.
4. Do not freeze the reagents. The kit should be stored between 2°C and 8°C.

5. The pouch containing the *Membrane Device* should be at room temperature before opening, and opened just before use. Keep the membrane devices dry before use.
6. Hold reagent bottles vertically to dispense reagents to ensure consistent drop size and correct volume.
7. Specimens and membrane devices should be handled and disposed of as potential biohazards after use. Wear disposable gloves when doing the test.
8. Membrane devices cannot be reused.
9. 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.
10. Microbial contamination of reagents may decrease the accuracy of the assay. Avoid microbial contamination of reagents by using sterile disposable pipettes if removing aliquots from reagent bottles.
11. 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*.

5. CALIBRATORS/STANDARDS

N/A

6. QUALITY CONTROL

6.1 Controls Used

Internal: A dotted blue line must be visible in the middle of the *Reaction Window*, below the “C” on every *Membrane Device* that is tested. The appearance of the blue control dots 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*. A clear background in the result area is considered an internal negative control. If the test has been performed correctly and reagents are working properly, the background will be white to give a discernible result.

External: The reactivity of the *C. DIFF QUIK CHEK COMPLETE*™ kit 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.

6.2 Control Preparation and Storage

NOTE: Date and initial all controls upon opening. Each container should be labeled with (1) substance name, (2) lot number, (3) date of preparation, (4) expiration date, (5) initials of tech, and (6) check for visible signs of degradation on of all items received.

Control	Positive and Negative External Controls
Storage	Store at 2-8°C
Stability	Stable until expiration date on vial label.
Preparation	Ready for use. Bring to room temperature.

6.3 Frequency

Internal controls are recorded for each patient test.

External positive and negative controls are tested with each new kit lot number or shipment or every 30 days, whichever is more frequent.

6.4 Tolerance Limits

Control	Expected Result
Internal Positive Control	A blue dotted line is visible in the middle of the <i>Reaction Window</i>
Internal Negative Control	Clear background in the result area
External Positive Control	Blue lines on the “Ag” and “Tox” sides of the <i>Reaction Window</i>
External Negative Control (Diluent)	A single blue dotted line is visible in the middle of the <i>Reaction Window</i> , below the “C” and no test lines are visible on the “Ag” side or the “Tox” side of the <i>Reaction Window</i>

- The following are guidelines for failed controls:

IF ...	THEN...
Any control does not produce the expected result	The test is invalid. Do not report patient results. Repeat testing. Do not report patient results until acceptable QC results are obtained. If repeat testing does not produce acceptable QC, then notify supervisor immediately.

Form revised 2/02/2007

6.5 Review Patient Data

Review patient data for unusual patterns, trends or distributions in patient results, such as an unusually high percentage of abnormal result.

6.6 Documentation

The results of the controls are documented on the appropriate manual QC log sheet.

6.7 Quality Assurance Program

- Quality Control cross-checks must be done with each new lot/shipment of kit using both internal and external controls.
- The laboratory participates in CAP proficiency testing.

7. EQUIPMENT and SUPPLIES

7.1 Assay Platform

N/A

7.2 Equipment

N/A

7.3 Supplies

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

8. PROCEDURE

NOTE: For all procedures involving specimens, buttoned lab coats, gloves, and face protection are required minimum personal protective equipment. Report all accidents to your supervisor.

The package insert for a new lot of kits must be reviewed for any changes before the kit is used. A current Package Insert is included as a Related Document.

8.1	Sample Preparation
1.	Bring all reagents and the required number of devices to room temperature before use.

8.1	Sample Preparation
2.	Set up and label one small test tube for each specimen and external controls as necessary.
3.	Using the black graduated dropper assembly, add 750 µL (2 nd graduation from the tip) <i>Diluent</i> to each tube for fecal specimens and the external <i>Positive Control</i> .
4.	Hold dropper bottle vertically and add one drop of <i>Conjugate</i> (red capped bottle) to each tube.
5.	Obtain one disposable plastic transfer pipette (supplied with the kit) for each sample – the pipettes have raised graduations at 25 µL, 400 µL and 500 µL.
6.	<p>Mix all specimens thoroughly regardless of consistency - it is essential that the specimens be evenly suspended before transferring.</p> <p>Liquid/Semi-solid specimens – pipette 25 µL of specimen with a transfer pipette (graduated at 25 µL, 400 µL and 500 µL) and dispense into the <i>Diluent/Conjugate</i> mixture. Use the same transfer pipette to mix the diluted specimen.</p> <p>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 2 mm diameter, the equivalent of 25 µL) of the specimen into the <i>Diluent/Conjugate</i> mixture. Emulsify the specimen using the applicator stick.</p> <p><i>NOTE: Transferring too little specimen, or failure to mix and completely suspend the specimen in the Diluent mixture, may result in a false-negative test result. The addition of too much fecal specimen may cause invalid results due to restricted sample flow.</i></p>
7.	<p>External Control Samples:</p> <p>External Positive Control - Hold dropper bottle vertically and add one drop of <i>Positive Control</i> (gray-capped bottle) to the appropriate test tube.</p> <p>External Negative Control - add 25 µL <i>Diluent</i> to the appropriate test tube.</p>
8.2	Procedure
1.	Obtain one <i>Membrane Device</i> per specimen, and one device per optional external positive or negative control as necessary. The foil bags containing the devices should be brought to room temperature before opening. Label each device appropriately and orient it on a flat surface so the “C. DIFF COMPLETE” print is at the bottom of the device, and the small <i>Sample Well</i> is located in the top right corner of the device.
2.	Mix each tube of diluted specimen thoroughly. Proper mixing can be achieved by vortexing or by repeated aspirations with the transfer pipette. Once a patient sample or <i>Positive Control</i> has been diluted in the <i>Diluent/Conjugate</i> mixture, it may be incubated at room temperature for any period of time up to 24 hours prior to addition to the <i>Membrane Device</i> .

Form revised 2/02/2007

8.2	Procedure
3.	Using a new transfer pipette, transfer 500 µL of the diluted sample-conjugate mixture into the <i>Sample Well</i> (smaller hole in the top right corner of the device) of a <i>Membrane Device</i> , making certain to expel the liquid sample onto the wicking pad inside of the <i>Membrane Device</i> . When loading the sample into the sample well, make sure that the tip of the transfer pipette is angled towards the <i>Reaction Window</i> (larger hole in the middle of the 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 <i>Reaction Window</i> . NOTE FOR SAMPLES THAT FAIL TO MIGRATE: Occasionally, a diluted fecal specimen cannot be tested because it clogs the membrane and the <i>Reaction Window</i> does not wet properly. If the diluted fecal specimen fails to migrate properly within 5 minutes of adding the sample to the <i>Sample Well</i> (i.e. the membrane in the <i>Reaction Window</i> does not appear to be completely wet), then add 100 µL (4 drops) of Diluent to the <i>Sample Well</i> and wait an additional 5 minutes (for a total of 20 minutes).
5.	After the incubation, add 300 µL of <i>Wash Buffer</i> to the <i>Reaction Window</i> using the graduated white dropper assembly (or equivalent). Allow the <i>Wash Buffer</i> to flow through the <i>Reaction Window</i> membrane and be absorbed completely.
6.	Add 2 drops of <i>Substrate</i> (white-capped bottle) to the <i>Reaction Window</i> . Read and record results visually after 10 minutes .

9. CALCULATIONS

N/A

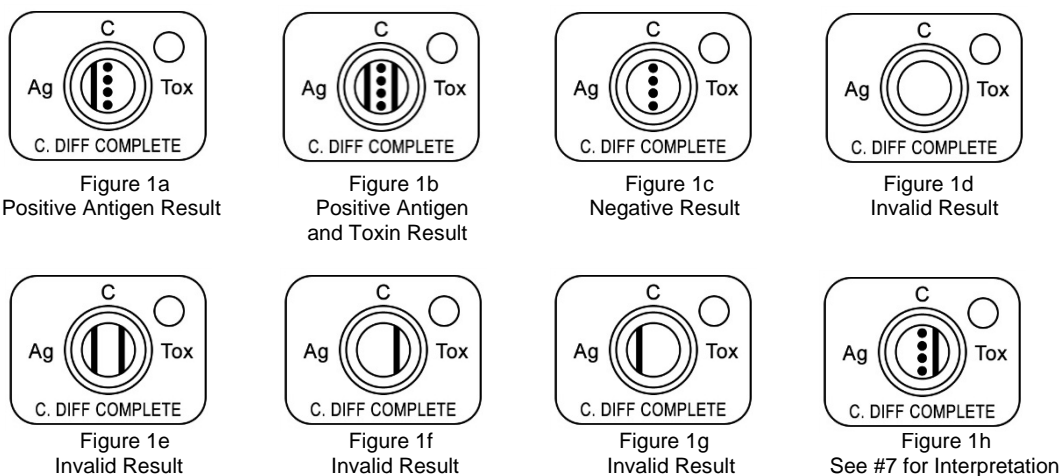
10. REPORTING RESULTS AND REPEAT CRITERIA

10.1 Interpretation of Results

1. Interpretation of the test is most reliable when the device is read immediately 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 blue dots in the middle of the *Reaction Window* representing the internal positive control. The appearance of any control dot(s) represents a valid internal control. Observe device for the appearance of blue lines on the “Ag” and Tox” sides of the *Reaction Window* representing the test lines. The lines may appear faint to dark in intensity.
3. **Positive Antigen (“Ag”) Result:** A positive antigen result may be interpreted at any time between the addition of *Substrate* and the 10-minute read time. For a positive antigen result, the blue “Ag” line and the dotted blue control line below “C” are visible (Figure 1a). 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 *C. difficile*.

4. **Positive Antigen and Toxin (“Tox”) Result:** If the antigen result is positive (i.e., a blue “Ag” line and a dotted blue control below “C” are visible), proceed to the interpretation of the toxin result. A positive toxin result may be interpreted at any time between the addition of *Substrate* and the 10-minute read time. For a positive toxin result, a blue “Tox” line is visible (Figure 1b). The line 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 *C. difficile* toxin.
5. **Negative Result: A test cannot be interpreted as negative or invalid until 10 minutes following the addition of Substrate.** A single blue dotted line is visible in the middle of the *Reaction Window*, below the “C” and no test lines are visible on the “Ag” side or the “Tox” side of the *Reaction Window* (Figure 1c). A negative result in the antigen portion indicates *C. difficile* antigen is either absent in the specimen or is below the detection limit of the test. A negative result in the toxin portion indicates *C. difficile* toxin is either absent in the specimen or is below the detection limit of the test.
6. **Invalid Result:** No lines are visible in the *Reaction Window* (Figure 1d). The test result is invalid if a blue dotted line is not present below the “C” at the completion of the reaction period (Figures 1e, 1f, 1g).
7. **Indeterminate Result:** A low percentage of specimens may test negative for antigen but positive for toxin. These samples should be considered indeterminate and retested using a fresh specimen (Figure 1h).

FIGURE 1: C. DIFF QUIK CHEK COMPLETE™ INTERPRETATION OF RESULTS



10.2 Rounding / Units of Measure / Clinically Reportable Range (CRR)

N/A

10.4 Resulting

Use function **MEM** to enter results.

Enter Shift (1, 2, or 3)

Worksheet: Use WIM2 for WAH or SIM2 for SGAH.

Test: <Enter>

Enter "A" (Accept)

Enter Accession number

Press <Enter> until Result screen displayed

Enter Results as listed below:

Test	Result	Report as	LIS code
<i>Clostridium difficile</i> GDH antigen (test code CDAG)	Negative	Negative	NEG
<i>Clostridium difficile</i> toxins A/B (test code CTOXIN)	Negative	Negative	NEG
<i>Clostridium difficile</i> GDH antigen (test code CDAG)	Positive	Positive	POS
<i>Clostridium difficile</i> toxins A/B (test code CTOXIN)	Positive	Positive	POS

IF	THEN
<i>Clostridium difficile</i> GDH antigen = Negative and <i>Clostridium difficile</i> toxins A/B = Negative	Report results.
<i>Clostridium difficile</i> GDH antigen = Positive and <i>Clostridium difficile</i> toxins A/B = Positive	Report results.
<i>Clostridium difficile</i> GDH antigen = Positive and <i>Clostridium difficile</i> toxins A/B = Negative	Report results. <i>C. difficile</i> PCR is reflexed on same specimen, label prints (test code XCDQL), and send to Chantilly.
<i>Clostridium difficile</i> GDH antigen = Negative and <i>Clostridium difficile</i> toxins A/B = Positive	Results are inconclusive, do NOT report. Repeat test. If repeat results are the same, order <i>C. difficile</i> PCR (XCDQL)

11. EXPECTED VALUES

11.1 Reference Ranges

Clostridium difficile toxins A/B – Negative

Clostridium difficile GDH antigen – Negative

11.2 Critical Values

Clostridium difficile toxins A/B and GDH antigen – Positive

11.3 Priority 3 Limit(s)

None established

12. CLINICAL SIGNIFICANCE

After treatment with antibiotics, many patients develop gastrointestinal problems ranging from mild diarrhea to severe pseudomembranous colitis. Many cases of the milder forms of gastrointestinal illness and most cases of pseudomembranous colitis are caused by toxigenic strains of *Clostridium difficile*. This organism is an opportunistic anaerobic bacterium that grows in the intestine once the normal flora has been altered by the antibiotic. Toxigenic strains of *C. difficile* carry the genes encoding the toxins while non-toxigenic strains do not carry the toxin genes. Disease onset is associated with the toxins that are produced by the toxigenic organism. The clinical symptoms associated with the disease are believed to be primarily due to toxin A, which is a tissue damaging enterotoxin. *C. difficile* also produces a second toxin, designated toxin B. Toxin B, which has been referred to as the cytotoxin of the organism, is the toxin detected by the tissue culture assay currently used by many laboratories. Toxigenic *C. difficile* strains produce both toxins, or only toxin B. The glutamate dehydrogenase of *C. difficile* is a good antigen marker for the organism in feces because it is produced in high amounts by all strains, toxigenic or non-toxigenic. The antigen can be detected in fecal specimens by using the C. DIFF QUIK CHEK COMPLETE™ test. A positive result in the test for the glutamate dehydrogenase of *C. difficile* confirms the presence of this organism in a fecal specimen; a negative result indicates the absence of the organism. A positive result in the test for toxins A and B confirms the presence of toxigenic *C. difficile*.

13. PROCEDURE NOTES

- **FDA Status:** Approved
- **Validated Test Modifications:** None
- The C. DIFF QUIK CHEK COMPLETE test is used to detect *C. difficile* antigen and toxin(s) in fecal specimens. The test confirms the presence of toxin 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. The C. DIFF QUIK CHEK COMPLETE test will detect levels of toxin A at ≥ 0.63 ng/mL, toxin B at ≥ 0.16 ng/mL, and glutamate dehydrogenase at ≥ 0.8 ng/mL.
- Fecal specimens are extremely complex. Optimal results with the C. DIFF QUIK CHEK COMPLETE test are obtained with specimens that are less than 24 hours old. Most undiluted specimens can be stored between 2°C and 8°C for 72 hours before significant degradation of the toxin is noted. If specimens are not assayed within this time period,

- they may be frozen and thawed. However, repeated freezing and thawing may result in loss in the immunoreactivity of antigen and toxins A and B.
- Some specimens may give weak reactions. This may be due to a number of factors such as the presence of low levels of antigen and/or toxin, the presence of binding substances, or inactivating enzymes in the feces. *Under these conditions, a fresh specimen should be tested.* Additional tests that may be used in conjunction with the C. DIFF QUIK CHEK COMPLETE test include culture with toxigenic testing or tissue culture cytotoxicity assay for the detection of *C. difficile* or its toxin(s).
 - The C. DIFF QUIK CHEK COMPLETE test is qualitative. The intensity of the color should not be interpreted quantitatively.
 - Colonization rates of up to 50% have been reported in infants. A high rate has also been reported in cystic fibrosis patients.
 - Colonic washes, barium enemas, laxatives, & bowel preparations can result in extensive dilution or additional substances in the specimen which may affect test performance.

14. LIMITATIONS OF METHOD

14.1 Precision

N/A

14.2 Interfering Substances

- The following substances had no effect on test results when present in feces in the concentrations indicated: mucin (3.5% w/v), human blood (40% v/v), barium sulfate (5% w/v), Imodium® (5% v/v), Kaopectate® (5% v/v), Pepto-Bismol® (5% v/v), steric/palmitic acid (40% w/v), Metronidazole (0.25% w/v), Vancomycin (0.25% w/v).
- Some isolates of *C. sordellii* may react in the C. DIFF QUIK CHEK COMPLETE test due to the production of immunologically related toxins. *C. sordelli* VPI 9048 produces toxins HT and LT, which are homologous to Toxins A and B respectively.
- Fecal specimens preserved in 10% Formalin, merthiolate formalin, sodium acetate formalin, or polyvinyl alcohol cannot be used.

14.3 Clinical Sensitivity/Specificity/Predictive Values

Refer to Tech Lab C. DIFF QUIK CHEK COMPLETE package insert.

15. SAFETY

The employee has direct responsibility to avoid injury and illness at work. Nearly all harmful exposures to infectious substances and chemicals, and other injuries, can be avoided with effective training and consistent safe work practices.

Become familiar with the Environmental Health and Safety (EHS) Manual to learn the requirements on working safely and protecting the environment from harm. Although lab

work typically focuses on the hazards of working with specimens and chemicals, we must also control other important hazards.

- Slips, trips, and falls cause many serious injuries. Please ensure that spills are cleaned quickly (to avoid slippery floors) and that you can see and avoid obstacles in your path.
- Ergonomic injuries result from performing tasks with too much repetition, force, or awkward position. Ergonomic injuries include strains and back injuries. Learn about ergonomic hazards and how to prevent this type of injury.
- Scratches, lacerations, and needlesticks can result in serious health consequences. Attempt to find ways to eliminate your risk when working with sharp materials.

Report all accidents and injuries immediately to your supervisor or the business unit Environmental Health and Safety Manager or Specialist.

16. RELATED DOCUMENTS

Current package insert for C. DIFF QUIK CHEK COMPLETE™
 C. DIFF QUIK CHEK COMPLETE Quality Control Log (AG.F69)

17. REFERENCES

1. Product Information Tech Lab C. DIFF QUIK CHEK COMPLETE package insert, RMS #91-525C-01, Issued: 4/2015.
2. Quinn CD, et al, "C. Diff Quik Chek complete enzyme immunoassay provides a reliable firstline method for detection of *Clostridium difficile* in stool specimens.", J Clin Microbiol. 2010; 48(2):6035.
3. Sharp SE, et al, "Evaluation of the C.Diff Quik Chek Complete Assay, a new glutamate dehydrogenase and A/B toxin combination lateral flow assay for use in rapid, simple diagnosis of clostridium difficile disease.", J Clin Microbiol. 2010; 48(6):20826.
4. Swindells J., et al, "Evaluation of diagnostic tests for Clostridium difficile infection.", J Clin Microbiol. 2010 Feb; 48(2):6068., Epub 2009 Dec 23.
5. "A Practical Guidance Document for the Laboratory Detection of Toxigenic Clostridium difficile", American Society for Microbiology, September 21, 2010.

18. REVISION HISTORY

Version	Date	Section	Reason	Reviser	Approval
000	4/22/2014	6.3	Clarified QC frequency	R. Master	R. Master
000	4/22/2014	16	Log moved from section 19	L. Barrett	R. Master
000	4/22/2014	Footer	Version # leading zero's dropped due to new EDCS in use as of 10/7/13.	L. Barrett	R. Master
1	9/28/2015	2	Added sentence to principle to be consistent with Package Insert	L. Wolff	R. Master
1	9/28/2015	3.1	Added special collection information about specimens containing barium, laxatives, enemas, bowel preps or colonic washes.	L. Wolff	R. Master

Form revised 2/02/2007

1	9/28/2015	3.2	Removed Cary-Blair transport as acceptable specimen	R. Master	R. Master
1	9/28/2015	4.1, 14.4, 17	Changed manufacturer's name from Wampole to TechLab	R. Master	R. Master
1	9/28/2015	4.2	Added note about substrate	R. Master	R. Master
1	9/28/2015	8.1	Added detail regarding the need to hold dropper bottles vertically and image of test device.	L. Wolff	R. Master
1	9/28/2015	8.1	Removed instruction for Cary-Blair transport	L. Barrett	R. Master
1	9/28/2015	13, 14	Moved some information from Limitations to Procedure Notes to be consistent with BPT SOP. Added caution about colonic washes, barium enemas, laxatives, and bowel preps.	R. Master	R. Master
1	9/28/2015	17	Updated references	R. Master	R. Master

19. ADDENDA

None