TRAINING UPDATE

Lab Location:	SGMC & WAH	**Date Distributed:**	1/3/2017
Department:	Core Lab	**Due Date:**	1/31/2017
		Implementation:	**2/1/2017**

DESCRIPTION OF PROCEDURE REVISION

Name of procedure:

C Diff Quik Chek Complete SGAH.M34 v4

C. DIFF QUIK CHEK COMPLETE QC Log AG.F69.4

Note: this has been converted to a system SOP

Description of change(s):

Section	Reason
4, 6	Remove individual section labeling instructions and add general one
6.2	Changed ext. QC frequency to 31 days
8.1	Remove prep for formed stool
10.3	Review data moved from section 6
15	Update to new standard wording

This revised SOP and FORM will be implemented on February 1, 2017

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

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**
Refer to the electronic signature page for approval and approval dates.		

Review		
Print Name	**Signature**	**Date**

Form revised 2/02/2007

TABLE OF CONTENTS

1. TEST INFORMATION

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

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

Department
Microbiology

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**	Non-formed raw stool (no preservative)
	-Other Acceptable	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	Reject the following samples and request an unpreserved, non-formed stool specimen: • Stool submitted on a swab • Stool submitted in transport media • Stool submitted in preservatives for O&P exams such as 10% formalin, merthiolate formalin, sodium acetate formalin, or polyvinyl alcohol preservatives • Unfrozen stool greater than 72 hours old • Rectal swabs • Specimens containing barium • Formed stool (stool that does not conform to the shape of the container)	
Compromising Physical Characteristics	N/A	
Other Considerations	Store specimens frozen (≤ -10°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 *Diluent* is NOT recommended.	

NOTE: Labeling requirements for all reagents, calibrators and controls include: (1) Open date, (2) Substance name, (3) Lot number, (4) Date of preparation, (5) Expiration date, (6) Initials of tech, and (7) Any special storage instructions. Check all for visible signs of degradation.

4. REAGENTS

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.

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

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

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 31 days, whichever is more frequent.

6.4 Tolerance Limits and Criteria for Acceptable QC

Control	**Expected Result**
Internal Positive Control	A blue dotted line is visible in the middle of the *Reaction Window*
Internal Negative Control	Clear background in the result area
External Positive Control	Blue lines on the "Ag" and Tox" sides of the *Reaction Window*
External Negative Control (Diluent)	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*

- 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.

6.5 Documentation

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

6.6 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.

8.1	Sample Preparation
1.	Bring all reagents and the required number of devices to room temperature before use.
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) *Diluent* to each tube for fecal specimens and the external *Positive Control*.
4.	Hold dropper bottle vertically and add **one drop** of *Conjugate* (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.

8.1	Sample Preparation
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 (graduated at 25 µL, 400 µL and 500 µL) 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 2 mm diameter, the equivalent of 25 µL) of the specimen into the *Diluent/Conjugate* mixture. Emulsify the specimen using the applicator stick.~~ *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.*
7.	**External Control Samples:** **External Positive Control** - Hold dropper bottle vertically and add one drop of *Positive Control* (gray-capped bottle) to the appropriate test tube. **External Negative Control** - add 25 µL *Diluent* to the appropriate test tube.

8.2	Procedure
1.	Obtain one *Membrane Device* 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 *Sample Well* 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 *Positive Control* has been diluted in the *Diluent/Conjugate* mixture, it may be incubated at room temperature for any period of time up to 24 hours prior to addition to the *Membrane Device*.
3.	Using a new transfer pipette, transfer **500 µL** of the diluted sample-conjugate mixture into the ***Sample Well*** (smaller hole in the top right corner of the device) of a *Membrane Device*, making certain to expel the liquid sample onto the wicking pad inside of the *Membrane Device*. When loading the sample into the sample well, make sure that the tip of the transfer pipette is angled towards the *Reaction Window* (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 *Reaction Window*. **NOTE FOR SAMPLES THAT FAIL TO MIGRATE:** Occasionally, a diluted fecal specimen cannot be tested because it clogs the membrane and the Reaction Window does not wet properly. If the diluted fecal specimen fails to migrate properly within 5 minutes of adding the sample to the Sample Well (i.e. the membrane in the Reaction Window does not appear to be completely wet), then add 100 µL (4 drops) of Diluent to the Sample Well and wait an additional 5 minutes (for a

8.2	Procedure
	total of 20 minutes).
5.	After the incubation, add **300 µL** of *Wash Buffer* to the ***Reaction Window*** using the graduated white dropper assembly (or equivalent). 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**.

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

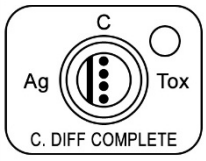

Figure 1a
Positive Antigen Result

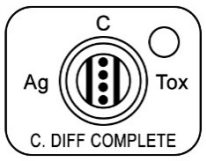

Figure 1b
Positive Antigen and Toxin Result

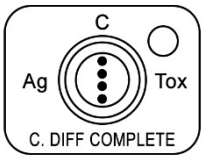

Figure 1c
Negative Result

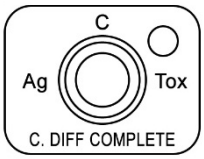

Figure 1d
Invalid Result

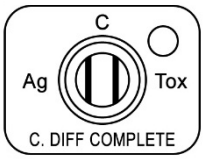

Figure 1e
Invalid Result

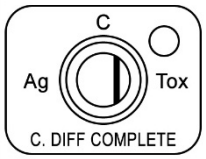

Figure 1f
Invalid Result

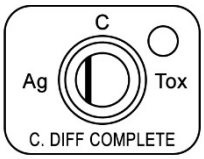

Figure 1g
Invalid Result

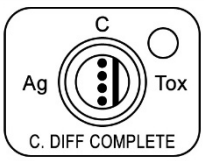

Figure 1h
See #7 for Interpretation

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

N/A

10.3 Review Patient Data

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

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
Clostridium difficile GDH antigen (test code CDAG)	Negative	Negative	NEG
Clostridium difficile toxins A/B (test code CTOXIN)	Negative	Negative	NEG
Clostridium difficile GDH antigen (test code CDAG)	Positive	Positive	POS
Clostridium difficile toxins A/B (test code CTOXIN)	Positive	Positive	POS

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

The following comment is automatically added to the report by the LIS when *C. difficile* GDH antigen is positive and *C. difficile* toxins A/B is negative:

C Diff PCR has been added

The following comment is automatically added to the report by the LIS when both *C. difficile* GDH antigen and toxins A/B are negative or both are positive:

C Diff PCR not indicated

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

Refer to your local and corporate safety manuals and Safety Data Sheet (SDS) for detailed information on safety practices and procedures and a complete description of hazards.

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
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
2	5/9/2016	3.2	Added formed stool to rejection criteria, reformatted rejection criteria	R. Master	R. Master
2	5/9/2016	11.3	Added report comments	L. Barrett	R. Master
3	12/6/2016	Header	Add WAH	L. Barrett	R. Master
3	12/6/2016	4, 6	Remove individual section labeling instructions and add general one	L Barrett	R. Master

Version	Date	Section	Reason	Reviser	Approval
3	12/6/2016	6.2	Changed ext. QC frequency to 31 days	L. Barrett	R. Master
3	12/6/2016	8.1	Remove prep for formed stool	L. Barrett	R. Master
3	12/6/2016	10.3	Review data moved from section 6	L. Barrett	R. Master
3	12/6/2016	15	Update to new standard wording	L. Barrett	R. Master

19. ADDENDA

None

Quest Diagnostics™

C. DIFF QUIK COMPLETE QUALITY CONTROL LOG

☐ Germantown Emergency Center
☐ Shady Grove Medical Center
☐ Washington Adventist Hospital

Next external QC is due = *Month* _____ *Circle day*

1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27 28 29 30 31

1. **External Positive and Negative Controls** are tested and documented with each new kit lot number or shipment or every 31 days, whichever is more frequent.
2. **Internal controls** must be documented with each patient test.
3. If QC results are not acceptable, document corrective action. Do not accept patient results before reviewing QC results for proper reactions.

Date	**Patient Name / MR#**	**Patient Result**		**Kit**	**Internal Controls**		**External Positive Controls**		**External Negative Control**	**Tech**
		Ag	**Tox**	**Lot # / Expire**	**Pos** Dotted Blue Line (Yes or No)	**Neg** Clear Background (Yes or No)	**Ag Result** (Pos)	**Toxin Result** (Pos)	**Diluent** (Neg)	
Weekly review:				Weekly review:			Weekly review:			
Weekly review:				Weekly review:			Monthly review:			