Inverness Medical CLIA Packet

The following materials are provided to all Inverness Medical Customers upon request to assure CLIA compliance upon completion of training by Inverness Medical Account Executives.

Included in this packet are the following:

♦ **CLIA Quality Control Information Letter** explaining Equivalent Quality Control (EQC) evaluation procedures and quality control requirements.

♦ **Equivalent Quality Control (EQC) Evaluation Record Sheet** to meet CLIA QC guidelines.

♦ **Verification Form** to meet CLIA accuracy and precision verification requirements (Not required for test systems in use prior to April 24, 2003).

♦ **Quality Control and Patient Record Forms** (available for your optional use) for routine quality control and patient result documentation.

♦ **Quality Assessment Plan** to meet CLIA requirements for monitoring pre-analytic, analytic, and post-analytic systems (Provided for laboratories who do not have established QA plan).

♦ **List of Important Test Procedure Steps** to eliminate sources of error.

♦ **Proficiency Test Information** Package:
  • Introduction to PT
  • Tips for Successful Performance
  • List of Proficiency Providers

♦ **Certificate of Training** to meet personnel guidelines for documentation of training.

♦ **Temperature Logs** for recording/monitoring refrigerated product storage temperatures.

♦ **Laboratory Procedure** specifically written according to the standards of CLSI Guidelines.

♦ **Competency Assessment** Forms for documentation of annual competency evaluations.

♦ Appendix: Material Safety Data Sheets (MSDS) to satisfy OSHA requirements.
Dear Customer,

Thank you for your interest in the Point of Care products from Inverness Medical. The following is a clarification in writing, of the Quality Control Requirements as mandated by CLIA for non-waived tests including the moderately complex Wampole™ C. DIFF QUIK CHEK COMPLETE® test.

Equivalent Quality Control (EQC) procedures may be used in lieu of performing daily external controls for the Wampole™ C. DIFF QUIK CHEK COMPLETE® test. Per the New CMS Interpretive Guidelines for the CLIA QC Standards, published January 2004, Sec. 493.1256 there are two options for evaluation of Quality Controls.

**Option 1:** Test Systems with Internal/Procedural Controls that Monitor the Entire Analytic Process

“The laboratory must perform the test system’s internal control procedure (s) in accordance with the manufacturer’s instructions (but not less frequently than once each day of testing) and test two levels of external control material daily for 10 consecutive days of testing. If the internal and external control results are acceptable throughout the evaluation process the laboratory may reduce the frequency of testing two levels of external control material from daily to once per calendar month.”

**Option 2:** Test Systems with Internal/Procedural Control(s) that Monitor a Portion of the Analytic Process.

“The laboratory must perform the test system’s internal control procedure (s) in accordance with the manufacturer’s instructions (but not less frequently than once each day of testing) and test two levels of external control material daily for 30 consecutive days of testing. If the internal and external control results are acceptable throughout the evaluation process the laboratory may reduce the frequency of testing two levels of external control material from daily to once per calendar week.”

**The EQC Evaluation Process for Option 1 and/or Option 2 must also comply with the following:**

- If internal or external QC is unacceptable during the evaluation the control must be repeated.
- If the repeat is not acceptable, the problem must be identified, and action taken. The laboratory must restart and successfully complete the evaluation process.
- The laboratory also must have an on-going assessment of successful proficiency test performance, a quality assessment plan, and competency evaluation documentation. Inverness Medical provides all the forms necessary for these assessments in the CLIA packet.

In addition, per the new CMS Interpretive Guidelines for the CLIA QC Standards, the laboratory must test external control materials with each new kit lot or shipment. If the external controls are acceptable the laboratory may continue monthly external controls for Option 1 or weekly external controls with Option 2 and daily internal control testing.

Per the Wampole™ C. DIFF QUIK CHEK COMPLETE® Package Insert, “A vertical dotted blue control line must be visible under the “C” portion of the Reaction Window on every Membrane Device that is tested. The appearance of the dotted 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 along the Membrane Device. The reactivity of the Wampole™ C. DIFF QUIK CHEK COMPLETE® test should be verified on receipt using the Positive Control and Negative Control (Diluent).”

Forms for QC documentation are available and may be provided to you by your Inverness Medical Sales Representative. If we may be of further service, please do not hesitate to call Technical Services at 877-441-7440.
Wampole™ C. DIFF QUIK CHEK COMPLETE® EQC Evaluation Record Sheet

Name of Facility: _________________________________

C. DIFF QUIK CHEK COMPLETE® Lot#___________________ Exp. Date_____________

CLIA EQC Procedure: The Laboratory may choose between two Equivalent Quality Evaluation Procedures for tests that contain internal positive and negative controls.

Option 1: Test the positive and negative external control material daily for 10 consecutive days of testing. If the internal and external control results are acceptable throughout the evaluation process the laboratory may reduce the frequency of testing external controls from daily to once per calendar month and with each new kit lot or shipment.

Option 2: Test the positive and negative external control material daily for 30 consecutive days of testing. If the internal and external control results are acceptable throughout the evaluation process the laboratory may reduce the frequency of testing external controls from daily to once per calendar week and with each new kit lot or shipment.

The internal control results should be recorded with each test. If the internal or external QC is unacceptable during the evaluation the control must be repeated. If the repeat is not acceptable the problem must be identified and action taken. The laboratory must restart and successfully complete the evaluation process. **Note:** If different operators perform the external control during the EQC evaluation period, this record sheet may also serve as the day-to-day, run-to-run, and the operator variance precision verification required by CLIA.

Record the Date, Control, Result, Internal Control Results, and the Performer's Initials. Internal Control = the dotted blue control line under the “C” portion of the Reaction Window.

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<th>Day #</th>
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## Wampole™ C. **DIFF QUIK CHEK COMPLETE®** EQC Evaluation Record Sheet

**Name of Facility:** ____________________________________________

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**Wampole™ C. DIFF QUIK CHEK COMPLETE® EQC Evaluation Record Sheet**

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Equivalent Quality Control (EQC) Record Sheet
Page 3 of 4
CLIA Wampole™ C. DIFF QUIK CHEK COMPLETE® Rev A
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# Wampole™ C. DIFF QUIK CHEK COMPLETE® EQC Evaluation Record Sheet

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Reviewed By: _________________________________   Date: _________________________________

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Equivalent Quality Control (EQC) Record Sheet
Page 4 of 4
CLIA Wampole™ C. DIFF QUIK CHEK COMPLETE® Rev A
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Establishment and Verification of Test Performance Specifications

Test System Verification Requirements

Laboratories are NOT required to verify or establish performance specifications for any test system used by the laboratory before April 24, 2003. Test systems introduced on or after April 24, 2003 are required to establish and verify test system specifications. Per the new CMS Interpretive Guidelines for the CLIA QC Standards, published January 2004, Sec. 493.1253 “Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results:”

“Demonstrate that it can obtain performance specification comparable to those established by the manufacturer for the following performance characteristics:

- Accuracy
- Precision
- Reportable range of test results for the test system.
- Verify that the manufacturer’s reference intervals (normal values) are appropriate for the laboratory’s patient population.”

Verification of accuracy may be accomplished by:

- Testing reference materials
- Comparing results of tests performed by the laboratory against the results of a reference method
- Or comparing split sample results with results obtained from a method, which is shown to provide clinically valid results.

Verification of precision may be accomplished by:

- Repeat testing of known patient samples over time
- Testing QC material in duplicate and over time
- Repeat testing of calibration materials over time.
- Must assess day-to-day, run-to-run and within-run variation as well as operator variance.

Laboratories may simultaneously verify multiple performance specifications, i.e., repeatedly test (precision) samples with known (accuracy) values.

The equivalent quality control (EQC) evaluation data may be used for documentation of day-to-day, run-to-run precision, as well as operator variance. Multiple operators must be included in the EQC testing in order to verify operator variance. Inverness Medical has included a verification form and a quality control form for recording EQC results in the CLIA packet for your use. The laboratory must save the EQC and Verification Forms as long as the test system remains in use in the laboratory.

The Wampole™ C. DIFF QUIK CHEK COMPLETE® test is a qualitative assay (results are reported as positive or negative); therefore the reportable range and reference interval verification is not applicable.

If we may be of further service, please do not hesitate to call Technical Services at 877-441-7440.
Wampole™ C. DIFF QUIK CHEK COMPLETE® Verification Form

Account Name: ________________________________
Address: ______________________________________
Telephone: _____________________________________

C. DIFF QUIK CHEK COMPLETE® LOT #: _____________

Date: __________________

Supervisor Signature: _____________________________

Record the results from 10 reference samples below.
Laboratories are NOT required to verify or establish performance specifications for any test system used by the laboratory before April 24, 2003.

Record the Sample #, the Wampole™ C. DIFF QUIK CHEK COMPLETE® results, Tester's Initials, and any comments. After the Wampole™ C. DIFF QUIK CHEK COMPLETE® results have been recorded (positive or negative) then record the Expected Results (positive or negative).

<table>
<thead>
<tr>
<th>Sample #</th>
<th>Expected Results</th>
<th>C. DIFF QUIK CHEK COMPLETE® Results</th>
<th>Tester's Initials</th>
<th>Comments</th>
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Reviewed By: ________________________________
**Wampole™ C. DIFF QUIK CHEK COMPLETE® Quality Control and Patient Record**

**Name of Facility: ____________________________**

Once the Equivalent Quality Control Evaluation Record Sheet has been successfully completed, CLIA requires external positive and negative controls with each new kit lot# or shipment AND following Option 1 or 2 below. In addition, manufacturer recommendations are to run Positive and Negative Controls with each new test kit. Use this coversheet with each new kit.

**Option 1** = Once per calendar month after completion of 10 consecutive day evaluation.

**Option 2** = Once per calendar week after completion of 30 consecutive day evaluation.

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<th>C. DIFF QUIK CHEK COMPLETE® Lot#__________</th>
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**Date Received__________**  **Received By Whom________________________**

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Reviewed by:______________________________  **Date:________________________**
**Wampole™ C. DIFF QUIK CHEK COMPETE® Quality Control and Patient Record**

**Lot Number**

Inverness Medical recommends that external positive and negative controls be run on each new test kit. Record the Date, Patient’s Name, Patient Test Results, Internal Control Results and the performer’s initials. Internal Control = the dotted blue control line under the “C” portion of the Reaction Window.

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Reviewed By: ___________________________ Date: __________________________

CLIA Wampole™ C. DIFF QUIK CHEK COMPLETE® Rev A
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Quality Assessment Plan

The following comprehensive plan has been established to assure the quality of the entire patient testing process. The purpose of these practices is to ensure that we provide reliable data that accurately reflects the patient's status.

The specific goals encompass the following:

1) To effectively monitor, manage, and assess the total testing process including pre-analytic, analytic, and post-analytic activities.

2) To assure the accurate, reliable, and prompt recording, reporting, and charting of patient test results.

3) To proactively evaluate the effectiveness of the established policies and procedures in order to identify and correct any potential or realized problems.

4) To assess laboratory personnel performance and competency periodically, and to ensure that appropriate training requirements commensurate with their positions and duties have been met, prior to their involvement in the patient testing process.

5) To ensure that adequate records describing the quality assessment practices and the quality of the analyses are documented, maintained, and reviewed.

General Policies

1) For all moderate or high complexity rated laboratory tests, we will participate in a CMS/CLIA approved proficiency testing program (PT).

2) This laboratory will maintain a quality control program to assure the continued precision and accuracy of laboratory results. When appropriate, the corrective action will be recorded in the designated areas of the test records.

3) All laboratory personnel will be trained, and the training documented by the laboratory director, prior to test performance.

4) The laboratory manual will include written test procedures for all tests listed in #1. These procedures will be reviewed on an annual basis by the Laboratory Director. All changes in protocol must be pre-approved by the Director prior to test performance.
Patient Test Management

All information pertaining to patient preparation and to specimen collection, preservation, and rejection are covered in the procedure manual for each test procedure.

Check one (✓)

- All patient test information will be maintained in the medical chart.
- All patient test information will be maintained on the test requisition and report form along with the laboratory test requisition and report log.

Proficiency Testing (PT)

The Laboratory will participate in an approved program for PT. All PT samples will be performed in the same manner as patient samples. The Director of the Laboratory will evaluate the returned PT results within 1 week of their return. Unacceptable, unsuccessful, or PT failures will result in documented corrective action on the Corrective Action Form. These records will be kept and filed with the quality assessment records.

Quality Control Assessment

The Laboratory Director reviews all quality control charts and logs on a monthly basis. All controls exceeding acceptable limits and not resolved by repeat testing will be reviewed by the Laboratory Director as soon as practical after the event. Corrective actions will be reviewed to ensure that appropriate and timely action was taken and the proper procedures were followed. Corrective actions should be documented on the Corrective Action Form, found in the manual. All Corrective Action Forms should be reviewed by the Director as soon as practical after the event.

These forms should be utilized whenever a problem arises that results in an "out of control" situation that is not resolved by repeating the test.

Comparison of Test Results

The Laboratory Director will ensure that instrument correlation studies are performed at least twice per year (when laboratories have >1 instrument system or methodology reporting like results (back-up methods), or > 1 testing site). Any test performed in the laboratory for which proficiency testing is not available will be verified at least twice per year. The results will be reviewed by the Laboratory Director.

Relationship of Patient Information to Test Results

The Laboratory Director will ensure that appropriate laboratory personnel monitor test requisitions for pertinent information to the patient's age, sex, and diagnosis. The results will also be compared to other readily available laboratory data (additional test parameters) on the patient. The accuracy and completeness of lab test reports will be monitored and evaluated.

If any requisitions or results appear inappropriate, proper consultation will be obtained from the Laboratory Director.
Personnel Assessment

If the laboratory has employees, the Laboratory Director will use personal observations to perform ongoing assessment of all employees of the laboratory to ensure competence of job performance. At least annually, the Director should review performance and provide a written review to be filed in the individual's personnel file. Opportunities for continuing education should be made available to employees and noted at the time of the review.

Communications

Effective communication is vital to the operation of the laboratory. The Laboratory Director will monitor the requisitioning and results of testing performed in the laboratory to ensure that any communication problems are corrected as soon as reasonably possible. A Corrective Action Form will be completed if a breakdown of the system occurs that is of significance and impacts patient care.

Complaints

Any complaints regarding the laboratory from patients or physicians should be reviewed and evaluated promptly by the Laboratory Director. If corrective actions are warranted, they should be documented on the Corrective Action Form and filed in the Quality Assessment Records.

Quality Assessment Reviews

QA reviews should be conducted on a regular basis for the purpose of monitoring and improving the quality of the testing process. Our reviews are conducted:

(✓) Check One:
___ Monthly
___ Bi-Monthly
___ Quarterly
___ Bi-annually
___ Annually

Quality Assessment Records

Quality Assessment Reviews should be filed with this plan and are available for periodical review by the Director of the Laboratory, or surveyors. All records are dated and initialed by the Staff performing the reviews, and the Laboratory Director.

Signature: ___________________________ 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.

<table>
<thead>
<tr>
<th>Quality Assessment Activity</th>
<th>Comments</th>
<th>Date/Initials</th>
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<tbody>
<tr>
<td>Patient Test Management: Evaluate criteria for specimen submission, handling, and rejection; test results requisitions and reporting, accuracy and reliability of reports.</td>
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<td>Quality Control: Assess calibration and control data, reference range verification, errors in reporting results, corrective actions taken with appropriate documentation records.</td>
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<td>Proficiency Testing: Review the effectiveness of corrective actions taken for unsatisfactory performance or failures.</td>
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<td>Comparison of Test Results: Review at least semi-annually comparative results for multiple methods, instruments, or site correlation's when more than one procedure exists.</td>
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<td>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.</td>
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<td>Personnel: Evaluate the effectiveness of policies and procedures for assuring employees competence of testing and reporting test results.</td>
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<td>Communications: Evaluate documented problems and corrective actions that occur between the laboratory and the authorized individual who orders or receives the test result.</td>
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<td>Complaint Investigation: Evaluate documented complaints and corrective actions.</td>
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<td>Quality Assessment Reviews with Staff: Document discussion with Staff regarding identified problems and corrective actions during the QA review.</td>
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### Corrective Action Form

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<th>Problem/Error</th>
<th>Corrective Action</th>
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Laboratory Performer: ____________________________  Date: ______________

Laboratory Director: ____________________________  Date: ______________
Wampole™ C. DIFF QUIK CHEK COMPLETE® Test

Important Procedure Steps

1. Bring all components of kit to room temperature before use. The pouch containing the Membrane Device should be at room temperature before opening, and opened just before use.

2. Fecal samples can be stored refrigerated 2°-8°C for up to 72 hours, but should be tested in <24 hours when possible. If the test cannot be performed within 72 hours of collection, specimens should be frozen (≤ -10°C). Diluted specimens should be stored for up to 24 hours and then discarded. Storing the fecal specimens in diluent is not recommended.

3. Specimens that have been preserved in 10% formalin, merthiolate formalin, sodium acetate formalin or polyvinyl alcohol cannot be used.

4. Add 750 µL of Diluent or 650 µL of Diluent for specimens in transport media to a tube. Add one drop of Conjugate.

5. Mix all specimens thoroughly regardless of consistency. This includes complete mixing of the specimen prior to transfer to Diluent as well as complete mixing of the diluted specimen prior to performing the assay.

6. Use the transfer pipette to add 25 of liquid specimen or a small portion of formed/solid specimens (2 mm diameter or equivalent of 25 µL) specimen to the Diluent/Conjugate mixture. Emulsify the specimen with the applicator stick. Fecal specimens in Cary Blair or C&S transport media - pipette 100 µL (2 drops from transfer pipette) of sample into the Diluent/Conjugate mixture.

7. If running external controls, dispense 1 drop from the positive control into the appropriate tube and 25 µL Diluent for the negative control into the appropriate tube.

8. Obtain one Membrane Device per specimen/control. Label each device appropriately and orient it on flat surface so “C. DIFF COMPLETE” print is at the bottom of the device and the small Sample Well is located in the top right corner.

9. Close each tube of diluted specimen and mix thoroughly. Once the patient or Positive Control is 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.

10. Using a new transfer pipette, transfer 500 µL of the diluted sample-conjugate mixture into the Sample Well (small hole in top right corner of the device) of a Membrane device expel the liquid onto the wicking pad inside. Make sure the pipette tip is angled towards the Reaction Window (larger hole in the middle of the device).

11. Incubate each membrane cassette at room temperature for 15 minutes – sample will wick through device. For samples that fail to migrate: if the diluted specimen fails to migrate after 5 minutes, add 100 µL (4 drops) of Diluent to the Sample Well and wait an additional 5 minutes (for a total of 20 minutes).

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

13. Add 2 drops of Substrate (white-capped bottle) to the Reaction Window. Read and record results visually after 10 minutes.
.... A Word about Proficiency Testing....

Proficiency testing (PT) is a type of *external* quality control. The practice of testing unknown specimens from an outside source provides an additional means to assure quality laboratory testing results. Although most labs perform daily *internal* quality control on samples with known values, external quality control provides important comparisons to determine the accuracy of your testing procedures.

The purpose of proficiency testing (PT) is to verify that the performance of each test site is in line with others performing the same analysis. Every four months, the PT provider sends test samples to their subscribers. The samples, whose values are unknown to the subscribers, are run by the testing personnel who return their results to the PT provider. The results are reviewed to determine whether each participant passes or fails performance levels established by federal and state agencies.
Tips for Successful PT Performance

♦ Strictly follow the PT provider's storage or handling requirement before testing PT specimens.

➢ Analyze PT specimens within the time frame provided by the PT provider.

➢ Contact the PT provider promptly when specimens are received damaged. You may be able to receive a replacement immediately.

➢ Avoid clerical error when filling out PT answer sheets. Be sure to enter the correct result next to the correct analyte on the answer form.

➢ Remember to identify the instrument or method you are using to perform your PT so that you are graded among your peer group.

➢ Make copies of all answer forms before submitting them to your PT provider.
Proficiency Test Providers

American Association of Bioanalysts (AAB)  
Proficiency Testing Service  
205 West Levee Street  
Brownsville, TX 78520-5596  
800-234-5315

College of American Pathologists (CAP)  
Surveys Program  
325 Waukegan Road  
Northfield, IL 60093-2750  
800-323-4040

American Academy of Family Physicians (AAFP)  
11400 Tomahawk Creek Pkwy  
Leawood, KS 66211-2672  
800-274-7911

College of American Pathologists (CAP)  
EXCEL Program  
325 Waukegan Road  
Northfield, IL 60093-2750  
800-323-4040

American Proficiency Institute (API)  
1159 Business Park Drive  
Traverse City, MI 49686  
800-333-0958

Medical Laboratory Evaluation (MLE)  
ACP-ASIM Services  
2011 Pennsylvania Avenue, NW  
Suite 800  
Washington, DC 20006-1834  
800-338-2746

Accutest  
P.O. Box 999  
Westford, MA

Some states provide their own in-state proficiency testing programs. Please contact your state CLIA office for more information.
# Certification of Training

This is to verify that the office staff and personnel responsible for running the Wampole™ C. DIFF QUIK CHEK COMPLETE® Test at ___________________________ have been thoroughly in-serviced on the test and the test procedure. This has included:

- Review of the package insert
- Demonstration of the product assay
- Successful performance of the Wampole™ C. DIFF QUIK CHEK COMPLETE® Test and interpretation of results

Names of the personnel who have been trained with the Wampole™ C. DIFF QUIK CHEK COMPLETE® Test and are responsible for reporting patient results:

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Signature of Medical Director(s) responsible for personnel and testing:

Signature [Date]

Signature [Date]

Inverness Medical Trainer [Date]
TEMPERATURE LOG

Equipment: __________________________
Name of Facility: _____________________
To be recorded at the beginning of each workday. Temperature Range: _____________

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To be recorded at the beginning of each workday. Temperature Range: 2° to 8°C

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TEMPERATURE LOG

Equipment: Lab Refrigerator
Name of Facility: _____________________
To be recorded at the beginning of each workday. Temperature Range: 35°F to 46°F

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©2009 Inverness Medical. All rights reserved.
This Procedural Manual 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. This Procedural Manual was prepared in accordance with the guidelines recommended by the Clinical and Laboratory Standards Institute, Wayne, PA 19087; CLSI Document GP2-A2. **Any modifications to this document are the sole responsibility of the Facility.**

**INTENDED USE**

The Wampole™ *C. DIFF QUIK CHEK COMPLETE®* test is a rapid membrane enzyme immunoassay for the simultaneous detection of *Clostridium difficile* glutamate dehydrogenase antigen and toxins A and B in a single reaction well. The test detects *C. difficile* antigen, glutamate dehydrogenase, as a screen for the presence of *C. difficile* and confirms the presence of toxigenic *C. difficile* by detecting toxins A and B in fecal specimens from persons suspected of having *C. difficile* disease. The test is to be used as an aid in the diagnosis of *C. difficile* disease. As with other *C. difficile* tests, results should be considered in conjunction with the patient history.
PRINCIPLE

The C. DIFF QUIK CHEK COMPLETE™ test uses antibodies specific for glutamate dehydrogenase and toxins A and B of C. difficile. 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 toxins 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. To perform the test, the sample 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, 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. The Reaction Window is subsequently washed with Wash Buffer, followed by the addition of Substrate. After a 10 minute incubation period, the “Ag” reaction is examined visually for the appearance of a vertical blue line on the “Ag” side of the Reaction Window. A blue line indicates a positive test. If the “Ag” is positive, then the “Tox” reaction should be examined visually for the appearance of a blue line on the “Tox” side of the Reaction Window. A blue line indicates a positive test. A positive “C” reaction, indicated by a vertical dotted blue line under the “C” portion of the Reaction Window, confirms that the test is working properly and the results are valid.

REAGENTS, EQUIPMENT, SUPPLIES:

Materials Provided

Membrane Devices – each pouch contains 1 device
Diluent (22 mL per bottle) – Buffered protein solution with graduated dropper assembly
Wash Buffer (12 mL per bottle) – Buffered solution with graduated dropper assembly
Substrate (3.5 mL per bottle) – Solution containing tetramethylbenzidine
Conjugate (2.5 mL per bottle) – Mouse monoclonal antibody specific for glutamate dehydrogenase coupled to horseradish peroxidase and goat polyclonal antibodies specific for toxins A and B coupled to horseradish peroxidase in a buffered protein solution
Positive Control (1 mL) – Antigen in a buffered protein solution
Disposable plastic transfer pipettes – graduated at 25 µL, 400 µL and 500 µL

Equipment/Supplies Required but Not Provided

Small test tubes (e.g., plastic Eppendorf tubes or glass tubes)
Applicator sticks
Disposable gloves for handling fecal samples
Timer
Vortex mixer
Pipettor and tips
Preparation:
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 optional external controls as necessary.
3. Using the black graduated dropper assembly, add 750 µL (2nd graduation from the tip) Diluent to each tube for fecal specimens. For specimens in transport media such as Cary Blair or C&S, add 650 µL of Diluent to the tube.
4. 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.

Graduated Transfer Pipette:

<table>
<thead>
<tr>
<th>Graduation</th>
</tr>
</thead>
<tbody>
<tr>
<td>500 µL</td>
</tr>
<tr>
<td>400 µL</td>
</tr>
<tr>
<td>25 µL</td>
</tr>
</tbody>
</table>

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.

   Fecal specimens in Cary Blair or C&S transport media - pipette 100 µL (2 drops from transfer pipette) of sample into the Diluent/Conjugate mixture.

7. Optional External Control Samples:

   External Positive Control - 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.

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.

Performance Considerations:
n/a

Calibration:
n/a

Storage Requirements:
The expiration date of the kit is given on the label. Expiration dates for each component are listed on the individual labels. The kit should be stored between 2° and 8°C.
SAMPLE
1. Standard collection and handling procedures used in-house for fecal specimens are appropriate. Specimens should be stored between 2°C and 8°C. Test specimens that are less than 24 hours old, whenever possible.
2. Store specimens frozen ($\leq -10^\circ$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.
3. Make sure that specimens are thoroughly mixed PRIOR to performing the assay.
4. Storing fecal specimens in the Diluent is NOT recommended.
5. Do not allow the fecal specimens to remain in the Diluent/Conjugate for $>24$ hours.

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. Use fecal specimens within 72 hours of collection to obtain optimal results. Specimens that are frozen may lose activity due to freezing and thawing. If using frozen specimens, thaw at room temperature.
7. Do not use specimens that have been preserved in 10% Formalin, merthiolate formalin, sodium acetate formalin or polyvinyl alcohol.
8. Specimens in transport media such as Cary Blair and C&S can be used as specified in the specimen preparation protocol.
9. Hold reagent bottles vertically to dispense 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. 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. 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.
14. 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.
15. If the Substrate reagent changes to a dark blue/violet color call technical services for replacement.
QUALITY CONTROL

**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 Wampole™ *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. Additional tests can be performed with the controls to meet the requirements of local, state and/or federal regulations and/or accrediting organizations.

TEST 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.  

```
Membrane Device     Sample Well
```

2. Close each tube of diluted specimen and mix thoroughly. Proper mixing can be achieved by vortexing or inverting the tube. 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 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.

CALCULATIONS:

n/a

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. 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**

<table>
<thead>
<tr>
<th>Positive Antigen Result</th>
<th>Positive Antigen and Toxin Result</th>
<th>Negative Result</th>
<th>Invalid Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Figure 1a</td>
<td>Figure 1b</td>
<td>Figure 1c</td>
<td>Figure 1d</td>
</tr>
<tr>
<td></td>
<td>Positive Antigen and Toxin Result</td>
<td>Invalid Result</td>
<td>Invalid Result</td>
</tr>
<tr>
<td>Figure 1e</td>
<td>Figure 1f</td>
<td>Figure 1g</td>
<td>Figure 1h</td>
</tr>
<tr>
<td></td>
<td>Invalid Result</td>
<td>Invalid Result</td>
<td>See #7 for Interpretation</td>
</tr>
</tbody>
</table>

**LIMITATIONS OF THE PROCEDURE:**

1. 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 $\geq0.63$ ng/mL, toxin B at $\geq0.16$ ng/mL, and glutamate dehydrogenase at $\geq0.8$ ng/mL.

2. 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.

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 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).
4. Fecal specimens preserved in 10% Formalin, merthiolate formalin, sodium acetate formalin, or polyvinyl alcohol cannot be used.
5. The C. DIFF QUIK CHEK COMPLETE™ test is qualitative. The intensity of the color should not be interpreted quantitatively.
6. Some isolates of C. sordellii may react in the C. DIFF QUIK CHEK COMPLETE™ test due to the production of immunologically related toxins (1).
7. Colonization rates of up to 50% have been reported in infants. A high rate has also been reported in cystic fibrosis patients (1,3).
8. The only non-C. difficile organism to react in the toxin portion of the C. DIFF QUIK CHEK COMPLETE™ test was Clostridium sordellii VPI 9048. This strain produces toxins HT and LT, which are homologous to toxins A and B, respectively.

PERFORMANCE CHARACTERISTICS

Clinical evaluation of the antigen portion of the C. DIFF QUIK CHEK COMPLETE™ test

The antigen portion of the C. DIFF QUIK CHEK COMPLETE™ test was compared to bacterial culture. Specimens included in the evaluation were submitted to the clinical laboratories for routine testing. The bacterial culture test was performed according to in-house procedures. The results are shown in Table 1.

<table>
<thead>
<tr>
<th>n = 1126</th>
<th>Bacterial Culture positive</th>
<th>Bacterial Culture negative</th>
</tr>
</thead>
<tbody>
<tr>
<td>C. DIFF QUIK CHEK COMPLETE™ Antigen Line Positive</td>
<td>201</td>
<td>62</td>
</tr>
<tr>
<td>C. DIFF QUIK CHEK COMPLETE™ Antigen Line Negative</td>
<td>21</td>
<td>842</td>
</tr>
</tbody>
</table>

95% Confidence Limits

- Sensitivity: 90.5% (85.7 – 93.9)
- Specificity: 93.1% (91.2 – 94.7)
- Predictive Positive Value: 76.4% (70.7 – 81.3)
- Predictive Negative Value: 97.6% (96.2 – 98.4)
- Correlation: 92.6% (91.8 – 93.4)

Discrepant samples were evaluated using current ELISA tests for C. difficile glutamate dehydrogenase. Twenty-nine of the 62 false positive samples were positive by another GDH test, and were considered true positives. Thirteen of the 21 false negative samples were negative by another GDH test, and were considered true negatives.

The antigen portion of the C. DIFF QUIK CHEK COMPLETE™ test was compared to the tissue culture assay for the detection of C. difficile toxin. Specimens included in the evaluation were submitted to the clinical laboratories for routine testing. The results are shown in Table 2. The antigen portion of the C. DIFF QUIK CHEK COMPLETE™ test detected 98.7% of the tissue culture-positive samples.
Table 2. Summary of clinical performance comparing *C. DIFF QUIK CHEK COMPLETE™* test to the tissue culture assay

<table>
<thead>
<tr>
<th></th>
<th>Tissue Culture positive</th>
<th>Tissue Culture negative</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>n = 1126</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td><em>C. DIFF QUIK CHEK COMPLETE™</em> Antigen Line Positive</td>
<td>154</td>
<td>109</td>
</tr>
<tr>
<td><em>C. DIFF QUIK CHEK COMPLETE™</em> Antigen Line Negative</td>
<td>2</td>
<td>861</td>
</tr>
</tbody>
</table>

Clinical evaluation of the toxin portion of the *C. DIFF QUIK CHEK COMPLETE™* test

The toxin portion of the *C. DIFF QUIK CHEK COMPLETE™* test was compared to the tissue culture assay at two clinical laboratories and in-house at TECHLAB®, Inc. Specimens included in the evaluation were submitted to the clinical laboratories for routine testing. The results are shown in Table 3.

Table 3. Summary of clinical performance comparing *C. DIFF QUIK CHEK COMPLETE™* test to the tissue culture assay

<table>
<thead>
<tr>
<th></th>
<th>Tissue Culture positive</th>
<th>Tissue Culture negative</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>n = 1126</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td><em>C. DIFF QUIK CHEK COMPLETE™</em> Toxin Line Positive</td>
<td>137</td>
<td>6</td>
</tr>
<tr>
<td><em>C. DIFF QUIK CHEK COMPLETE™</em> Toxin Line Negative</td>
<td>19</td>
<td>964</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th></th>
<th>95% Confidence Limits</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sensitivity</td>
<td>87.8%</td>
</tr>
<tr>
<td>Specificity</td>
<td>99.4%</td>
</tr>
<tr>
<td>Predictive Positive Value</td>
<td>95.8%</td>
</tr>
<tr>
<td>Predictive Negative Value</td>
<td>98.1%</td>
</tr>
<tr>
<td>Correlation</td>
<td>97.8%</td>
</tr>
</tbody>
</table>

Discrepant samples were evaluated using current ELISA tests for toxins A and B.

Five of the 6 false positive samples were positive by ELISA and were considered true positives.

Twelve of the 19 false negative samples were negative by ELISA and were considered true negatives.

NOTE: For complete details and performance of this product, refer to the package insert provided with the test kit.
REFERENCES:


Contact Information:

Inverness Medical
2 Research Way, Princeton, NJ 08540 USA
Wampole™ C. DIFF QUIK CHEK COMPLETE® Competency Assessment

...A Word about Personnel Requirements...

For laboratories performing moderate complexity testing certain personnel requirements must be met. The laboratory must have:

- Laboratory Director to provide overall management and direction
- Technical Consultant to provide technical oversight
- Clinical Consultant to provide clinical consultation
- Testing Personnel to perform all functions required for the tests performed

All responsibilities and qualifications must be in accordance with the CLIA ’88 Rules and Regulations, as published in the October 1, 2000 Code of the Federal Register CFR 42, Sections 493.1403 through 493.1425. The Laboratory Director, if qualified, may perform the duties of the Technical Consultant, Clinical Consultant, and Testing Personnel. A summary of personnel qualification requirements can be found in Table 1.

Personnel Files

Personnel files must be maintained on all current employees. At minimum, technical personnel records must include all of the following items:

- current certification or license, if required by state
- copy of high school diploma or equivalent
- documentation of training for the tests performed
- records of continuing education
- documentation of competency assessments

Competency Assessment

The Technical Consultant is responsible for the technical and scientific oversight of the lab. Included in these responsibilities is providing regular training, appropriate education, and evaluating and maintaining competency of testing personnel. Evaluating and documenting the performance of the individuals responsible for moderate complexity testing should be done at least semiannually during the first year the individual tests patient specimens. Thereafter, evaluations must be performed at least annually unless test methodology or instrumentation changes, in which case, prior to reporting patient test results; the individual’s performance must be reevaluated to include the use of the new test methodology or instrumentation.

The procedures for evaluating the competency of the staff must include but are not limited to:

1. Direct observations of routine patient test performance, including patient preparation, if applicable, specimen handling, processing and testing.
2. Monitoring the recording and reporting of test results.
3. Review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records.
5. Assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples.
6. Assessment of problem solving skills.

In addition to evaluating the pre-analytical, analytical, and post-analytical phases of a test method, evaluation of competency may also include a written quiz.
**Competency Assessment Tools**

As an Inverness Medical customer you are provided with the following tools to help meet some of your CLIA Personnel Requirements:

- The Training Certificate in the CLIA packet can be used as documentation that appropriate training has been provided to all testing personnel for the *C. DIFF QUIK CHEK COMPLETE®* test.
- We have provided you with a written quiz that can be administered to all testing personnel as part of their competency assessment.
- A Competency Assessment Checklist has been created that can be used to verify and document that all areas of competency for the *C. DIFF QUIK CHEK COMPLETE®* test have been evaluated.

**Table 1 – CLIA '88 Personnel Qualification Requirements**

<table>
<thead>
<tr>
<th>Role</th>
<th>Degree Required</th>
<th>Training/Experience</th>
</tr>
</thead>
<tbody>
<tr>
<td>Laboratory Director*</td>
<td>Pathologist</td>
<td>0</td>
</tr>
<tr>
<td></td>
<td>M.D./D.O./Podiatrist</td>
<td>• 1 year directing or supervising non-waived laboratory testing; or</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Have 20 CME credit hours in laboratory practice; or</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• 1 year laboratory training obtained during residency</td>
</tr>
<tr>
<td></td>
<td>Ph.D. †</td>
<td>• Board certified – 0</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Non board certified - 1 year directing or supervising non-waived laboratory testing</td>
</tr>
<tr>
<td></td>
<td>M.S. ††</td>
<td>• 1 year laboratory training or experience in non-waived testing and</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• 1 year of supervisory laboratory experience in non-waived testing</td>
</tr>
<tr>
<td></td>
<td>B.S. ††</td>
<td>• 2 years laboratory training or experience in non-waived testing; and</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• 2 years of supervisory laboratory experience in non-waived testing</td>
</tr>
<tr>
<td>Technical Consultant*</td>
<td>Pathologist</td>
<td>0</td>
</tr>
<tr>
<td></td>
<td>M.D./D.O./Podiatrist; or Ph.D. or M.S. ††</td>
<td>1 year laboratory training or experience in non-waived testing in the designated specialty or subspecialty areas for which the Technical Consultant is responsible</td>
</tr>
<tr>
<td></td>
<td>B.S. ††</td>
<td>2 years laboratory training or experience in non-waived testing in the designated specialty or subspecialty areas for which the Technical Consultant is responsible</td>
</tr>
<tr>
<td>Clinical Consultant</td>
<td>Pathologist</td>
<td>0</td>
</tr>
<tr>
<td></td>
<td>M.D./D.O./Podiatrist</td>
<td>• 1 year directing or supervising non-waived laboratory testing, or</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Have 20 CME credit hours in laboratory practice, or</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• 1 year laboratory training obtained during residency</td>
</tr>
<tr>
<td></td>
<td>Ph.D. † and board certified</td>
<td>0</td>
</tr>
<tr>
<td>Testing Personnel*</td>
<td>Pathologist, Ph.D., M.S., B.S., Associates Degree††, or medical laboratory technology</td>
<td>0</td>
</tr>
<tr>
<td></td>
<td>High School Diploma with documented training</td>
<td>0</td>
</tr>
</tbody>
</table>

*Must possess a current license issued by the State in which the laboratory is located, if such licensing is required.
† Degree specializing in chemical, physical, biological, or clinical laboratory science.
†† Degree specializing in chemical, physical, biological, or clinical laboratory science or medical technology.

**References:**


**Attachments:**

- Competency Assessment Answer Key
- Competency Assessment Personnel Checklist
- Competency Assessment Quiz
Wampole™ C. DIFF QUIK CHEK COMPLETE® Quiz Answer Key

1. F The C. DIFF QUIK CHEK COMPLETE® kit can be stored at room temperature.

2. T The C. DIFF QUIK CHEK COMPLETE® test device should be at room temperature before opening, and opened just before use.

3. F External controls must be treated similar to patient specimens and diluted before use.

4. T Fecal samples can be stored at 2°C -8°C for up 72 hours, but should be tested within 24 hours of collection.

5. T Cary Blair and C&S transport media are acceptable.

6. F Membrane Cassettes should be placed face up on a damp paper towel before use

7. F The test can be read within three minutes of sample addition

8. T The C. DIFF QUIK CHEK COMPLETE® package insert recommends external positive and negative controls upon receipt of kit.

9. F Specimens can be stored in diluent for up to 48 hours at room temperature.

10. T The C. DIFF QUIK CHEK COMPLETE® test is qualitative. The intensity of the color should not be interpreted quantitatively.
# Testing Personnel Competency Assessment

**Employee:** ____________________________  
**Date:** ____________________________

**Test Method:** *Wampole™ C. DIFF QUIK CHEK COMPLETE®* CLIA Packet Test

<table>
<thead>
<tr>
<th>Procedure</th>
<th>Satisfactory</th>
<th>Unsatisfactory</th>
<th>Not Applicable</th>
<th>Comments/Corrective Actions</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Observation of Test Performance:</strong></td>
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<td><strong>Assessment of Problem Solving Skills</strong></td>
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(Attach all supporting documents)

**Evaluator:** ____________________________  
**Date:** ____________________________

**Employee:** ____________________________  
**Date:** ____________________________
Wampole™ C. DIFF QUIK CHEK COMPLETE® Quiz

Name: ___________________________________________________________

Date: ___________________________________________________________

Circle T (True) or F (False) for each Question:

1. The C. DIFF QUIK CHEK COMPLETE® test kit may be stored at room temperature. T  F

2. The C. DIFF QUIK CHEK COMPLETE® test device should be at room temperature before opening, and opened just before use. T  F

3. External controls must be treated similar to patient specimens and diluted before use. T  F

4. Fecal samples can be stored at room temperature and run within two weeks. T  F

5. Cary Blair and C&S transport media are acceptable. T  F

6. Membrane Cassettes should be placed face up on a damp paper towel before use. T  F

7. The test can be read within three minutes of sample addition T  F

8. The C. DIFF QUIK CHEK COMPLETE® package insert recommends external positive and negative controls upon receipt of kit. T  F

9. Specimens can be stored in diluent for up to 48 hours at room temperature. T  F

10. The C. DIFF QUIK CHEK COMPLETE® is a quantitative test based on the intensity of the color. T  F

Reviewed By: ________________________________ Date: ______________
1. Identification of the substance / preparation and of the company / undertaking

1.1. Identification of the substance or preparation

Product Name: C. DIFF QUIK CHEK COMPLETE®
Cat. Number: 30525C/30550C/T30525C/T30550C
Composition: Conjugate, Diluent, Positive Control, Wash Buffer, Substrate, Membrane Device

1.2. Use of the substance / preparation

The C. DIFF QUIK CHEK COMPLETE® test is a rapid immunoassay for the simultaneous detection of C. difficile glutamate dehydrogenase antigen and toxins A and B in fecal specimens. FOR IN VITRO DIAGNOSTIC USE.

1.3. Company / undertaking identification

Manufactured by: TECHLAB®, Inc.
Distributed by: Inverness Medical
2001 Kraft Drive
Blacksburg, VA 24060
2 Research Way
Princeton, NJ 08540

1.4. Emergency telephone: 1-800-222-1222 (Poison Control)

2. Hazard Identification

All kit components have been classified as non-hazardous according to EC Directive 67/548 EC and 1999/45/EEC.

The Conjugate, Diluent, and Positive Control contain material of animal origin: Animal proteins are potentially infectious
3. Composition / information on ingredients

<table>
<thead>
<tr>
<th>Product</th>
<th>Hazardous Chemicals</th>
<th>CAS No.</th>
<th>%</th>
<th>EC No.</th>
<th>Classification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Positive Control</td>
<td>Animal proteins</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>Diluent</td>
<td>Animal proteins</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>Conjugate</td>
<td>Animal proteins</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>Conjugate, Wash Buffer,</td>
<td>ProClin300*</td>
<td>N/A</td>
<td>&lt;0.05</td>
<td>N/A</td>
<td>T; R23/24/25 C; R34 R43 N; R50/53</td>
</tr>
</tbody>
</table>

*Active ingredient of ProClin300 is 3:1 mixture of 5-chloro-2-methyl-4-isothiazolin-3-one and 2-methyl-4-isothiazolin-3-one approximately 0.0014%.

For the wording of the listed risk phrases refer to section 16.

4. First Aid Measures

Symptoms of poisoning may occur even after several hours; therefore, medical observation for at least 48 hours after the accident is recommended.

- **After inhalation:** Remove person to fresh air. If required, provide artificial respiration. Keep patient warm. Consult doctor if symptoms persist.
- **After skin contact:** Rinse immediately with water for 15 minutes. If skin irritation continues, consult a doctor.
- **After eye contact:** Rinse open eye with water for 15 minutes under running water. Then consult doctor.
- **After swallowing:** Induce vomiting, only if person affected is fully conscious. Wash out mouth with water. Drink large quantities of water. Seek medical attention immediately.
- **The following symptoms may occur:** Headache, cramps, dizziness, nausea, diarrhea.

5. Fire Fighting Measures

- **Suitable extinguishing agents:** Product itself does not burn. Use fire fighting measures that suit the environment.
- **Special hazards caused by the material, its products of combustion or flue gases:** No data available.
- **Protective equipment:** No special measures required. In case of burning of a larger amount: Wear breathing equipment and protective suit to avoid contact with skin and eyes.

6. Accidental Release Measures

- **Person-related safety precautions:** Do not inhale vapors. Prevent contact with skin and eyes.
- **Measures for environmental protection:** Do not allow product to reach sewage system or water bodies.
- **Measures for cleaning / collecting:** Ensure adequate ventilation. Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust). Dispose of contaminated material as waste according to item 13.
7. Handling and Storage

7.1. Handling

- Information for safe handling:
  Open and handle container with care. Prevent formation of aerosols.
- Information about protection against explosions and fires:
  In cases of fire formation of dangerous fumes possible.

7.2. Storage

- Requirements to be met by storerooms and containers:
  No special requirements.
- Information about storage in one common storage facility:
  Not required.
- Further information about storage conditions:
  Keep container tightly sealed.
  Store refrigerated (2-8 °C).
- Storage class:
  Not inflammable liquids – storage according to the national regulations.

7.3. Specific Use(s):

N/A

8. Exposure Controls and Personal Protection

8.1. Exposure limit values

Not available for this preparation.

8.2. Exposure controls

8.2.1. Occupational exposure controls

8.2.1.1. Respiratory protection
  Not required

8.2.1.2. Hand protection
  Compatible chemical-resistant gloves.
  For the selection of glove material, breakthrough times and other test results are not available for this specific preparation.

8.2.1.3. Eye protection
  Safety goggles.

8.2.1.4. Skin protection
  Protective work clothing.

8.2.2. Environmental exposure controls

No data available.

9. Physical and Chemical Properties

- General information
  Form: Liquid preparations
  Color: Various
  Smell: Characteristic
10. Stability and Reactivity:

- **Conditions to be avoided:**
  No decomposition if used according to specifications.

- **Materials to avoid:**
  N/A

- **Hazardous decomposition products:**
  N/A

11. Toxicological Information

**Active ingredient of ProClin 300:**

- **Acute toxicity**
  - LD50 Oral - rat - 862 mg/kg
  - LD50 Dermal - rabbit - 2,800 mg/kg

- **Irritation and corrosion**
  - On the skin: rabbit - Corrosive
  - On the eye: rabbit - Corrosive

- **Sensitization:** May cause allergic skin reaction.

**Subacute to chronic toxicity:** IARC: No component of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.

**Potential Health Effects**

- **Inhalation** May be harmful if inhaled. Material is extremely destructive to the tissue of the mucous membranes and upper respiratory tract.
- **Skin** May be harmful if absorbed through skin. Causes skin burns.
- **Eyes** Causes eye burns.
- **Ingestion** Harmful if swallowed. Causes burns.
- **Aggravated Medical Condition** May provoke asthmatic response in persons with asthma who are sensitive to airway irritants.
- **Target Organs** Liver

12. Ecological Information

**12.1. Ecotoxic effects**

No data available
12.2. Mobility
No data available

12.3. Persistence and degradability
No data available

12.4. Bioaccumulative potential
Log Pow = no data available
BCF = no data available

12.5. Other adverse effects
An environmental hazard cannot be excluded in the event of unprofessional handling or disposal.

13. Disposal Considerations

- **Product**
  **Recommendation:**
  Must not be disposed of together with household garbage.
  Do not allow product to reach sewage system.
  Residues of chemicals and preparations are generally considered hazardous waste. The disposal of this kind of waste is regulated through national and regional laws and regulations. Contact your local authorities or waste management companies, which will give advice on how to dispose of hazardous waste.

- **Uncleaned packagings**
  **Recommendation:** Disposal must be made according to official regulations.
  **Recommended cleaning agent:** Water, if necessary with cleaning agent.

14. Transport Information

- **Land transport ADR / RID and GGVS / GGVE (cross-border/domestic)**
  ADR / RID-GGV / E Class: N/A

- **Maritime transport IMDG / GGVSea**
  IMDG/ GGVSea Class: N/A
  Marine pollutant: Yes

- **Air Transport ICAO-TI and IATA-DGR**
  ICAO / IATA Class: N/A

- **Transport / Additional information:**
  Because of small volumes no classification as dangerous goods according to above regulations.
15. Regulatory Information

- **Designation according to EC guidelines:**
  The product has been classified as non-hazardous and labeled in accordance with EC Directives / Ordinance on Hazardous Materials.
  **Code letter and hazard designation of product:** N/A
  **Hazard-determining components of labeling:** N/A

- **National regulations:**
  Please ask your national/regional authorities.

16. Other Information

The above information and recommendations are believed to be correct as of the date of this Material Safety Data Sheet but shall not be taken to be all-inclusive and shall be used only as a guide. All chemicals and preparations may present unknown hazards and should be used with caution. TECHLAB®, Inc. shall not be held liable for any damage resulting from handling or from contact with the above product.

All animal products and derivatives have been collected from healthy animals. Bovine components (if any) originate from countries where BSE has not been reported.

- ** Relevant R-phrases:**
  R23/24/25  Toxic by inhalation, in contact with skin and if swallowed.
  R34       Causes burns.
  R43       May cause sensitization by skin contact.
  R50/53    Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

- **Abbreviations:**
  N/A = not applicable

**Effective:** 04/2009
**Replaces version from:** 09/2008
**Modification versus previous version:** Updated for Inverness Medical Information

*C. DIFF QUIK CHEK COMPLETE®* is a trademark of TECHLAB®, Inc.