K082499

7. 510(k) SUMMARY

Contact Information

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Product and Trade Name *C. DIFF QUIK CHEK COMPLETE™*

Classification 21 CFR 866.2660

Predicate Devices

For the detection of GDH antigen

- *C. difficile* Culture Media such as cycloserine - cefoxitin fructose agar (CCFA) is available commercially from various sources.
- *C. DIFF QUIK CHEK®*
- *C. DIFF CHEK™ – 60*
- BD CULTURETTE™ CDT™
- ImmunoCard® *C. difficile* EIA

For the detection of Toxins A and B

- *C. DIFFICILE TOX-B TEST* and *C. difficile* Toxin/Antitoxin along with human foreskin monolayer tissue cultured cells (Diagnostic Hybrids, Inc.). Alternatively, clinical laboratories may use their own tissue cultured monolayer cells.
- *TOX A/B QUIK CHEK®*
- *C. DIFFICILE TOX A/B II™*
- Premier™ Toxins A&B
- ProSpecT® Clostridium difficile Toxin A/B
- Immuno*Card®* Toxins A&B
- X/pect™ Clostridium difficile Toxin A/B

For the simultaneous detection of GDH antigen and Toxin A

- Biosite Triage® Micro *Clostridium difficile* Panel

Intended Use

The *C. DIFF QUIK CHEK COMPLETE™* test is a rapid membrane enzyme immunoassay for the simultaneous detection of *C. 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 the 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.

Device Description

The *C. DIFF QUIK CHEK COMPLETE™* test uses antibodies specific for glutamate dehydrogenase (GDH) and Toxins A and B of *C. difficile*. The device contains a *Reaction Window* with two solid lines and a dotted line of immobilized antibodies. The Antigen line ("Ag") contains antibodies against *C. difficile* GDH. The Toxin line ("Tox") contains antibodies against *C. difficile* toxins A and B. The dotted line, representing a control line ("C"), contains anti-HRP antibodies. The *Conjugate* consists of antibodies to GDH, toxin A, and toxin B coupled to horseradish peroxidase. To perform the test, the fecal specimen is diluted with *Diluent*, and *Conjugate* is added to the diluted sample. 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 GDH, toxin A or toxin B in the sample binds to the corresponding antibody-peroxidase conjugate. The antigen-antibody complexes migrate through a filter pad to a membrane where they are captured by the immobilized anti-GDH, anti-toxin A or Anti-toxin B antibody in the line. The *Reaction Window* is subsequently washed with *Wash Buffer*, followed by the addition of *Substrate*. After a 10-minute incubation, the "Ag" and "Tox" reaction is examined visually for the appearance of a blue line. A blue line indicates a positive test. A positive "C" reaction, indicated by a blue dotted line, confirms that sample and all reagents were added in proper sequence and volume, that reagents were active at the time of performing the assay, and that proper sample migration occurred.

Comparative Information of Equivalent Devices
For detection of GDH antigen:

Characteristics	510(k) Numbers	Intended Use	Format	Materials	Target Population
C. difficile Cacterial Culture	Used before 1976, 510(k) not available.	Detection of *C. difficile* organism in fecal specimens	Bacterial culture	Specific selective media, CCFA[a] plates and CC BHI[b] broth	Persons suspected of having *C. difficile* disease
C. DIFF CHEK™ - 60	K030992	Detection of *C. difficile* organism in fecal specimens	ELISA	Highly specific antibodies against *C. difficile* GDH	Persons suspected of having *C. difficile* disease
BD CULTURETTE™ CDT™	K870864	Detection of *C. difficile* organism in fecal specimens	Latex agglutination	Antibodies against *C. difficile* GDH and other proteins	Persons suspected of having *C. difficile* disease
Triage® Micro *C. difficile* Panel, GDH portion	K974881	Detection of *C. difficile* organism in fecal specimens	Flow through membrane test	Highly specific antibodies against *C. difficile* GDH	Persons suspected of having *C. difficile* disease
ImmunoCard® *C. difficile* EIA	K924979	Detection of *C. difficile* organism in fecal specimens	Lateral flow membrane test	Highly specific antibodies against *C. difficile* GDH	Persons suspected of having *C. difficile* disease
C. DIFF QUIK CHEK® test	K053572	Detection of *C. difficile* organism in fecal specimens	Rapid membrane	Highly specific antibodies against *C. difficile* GDH	Persons suspected of having *C. difficile* disease

a, CCFA, cycloserine - cefoxitin fructose agar plates
b, CC-BHI, cycloserine - cefoxitin brain-heart infusion liquid media

For detection of toxins A and B:

Characteristics	510(k) Numbers	Intended Use	Format	Materials	Target Population
Tissue culture assay (*TOX-B TEST*)	K935296	Detection of *C. difficile* toxin in fecal specimens	Tissue culture	Cell monolayer, specific neutralizing antiserum	Persons suspected of having *C. difficile* disease
C. DIFFICILE TOX A/B II™	K003306 and K030404	Detection of *C. difficile* toxin in fecal specimens	Microassay ELISA	Highly specific antibodies against *C. difficile* toxins A and B	Persons suspected of having *C. difficile* disease
Premier™ Toxins A&B	K993914	Detection of *C. difficile* toxin in fecal specimens	Microassay ELISA	Highly specific antibodies against *C. difficile* toxins A and B	Persons suspected of having *C. difficile* disease
ProSpecT® Clostridium difficile Toxin A/B	K033479	Detection of *C. difficile* toxin in fecal specimens	Microassay ELISA	Highly specific antibodies against *C. difficile* toxins A and B	Persons suspected of having *C. difficile* disease
Immuno*Card*® Toxins A&B	K041003	Detection of *C. difficile* toxin in fecal specimens	Rapid membrane	Highly specific antibodies against *C. difficile* toxins A and B	Persons suspected of having *C. difficile* disease
X/pect™ Clostridium difficile Toxin A/B	K041951	Detection of *C. difficile* toxin in fecal specimens	Rapid membrane	Highly specific antibodies against *C. difficile* toxins A and B	Persons suspected of having *C. difficile* disease
TOX A/B QUIK CHEK® test	K050891	Detection of *C. difficile* toxin in fecal specimens	Rapid membrane	Highly specific antibodies against *C. difficile* toxins A and B	Persons suspected of having *C. difficile* disease

Summary of Performance Data
Clinical Accuracy
For GDH antigen

The following tables show a summary of the clinical performance of the GDH antigen portion of the *C. DIFF QUIK CHEK COMPLETE™* test. The discrepant samples generated from the *C. DIFF QUIK CHEK COMPLETE™* and bacterial culture assay were resolved using the *C. DIFFICILE CHEK™ - 60* ELISA, which detects GDH antigen. The protocols are presented in the Appendices. The results show that the *C. DIFF QUIK CHEK COMPLETE™* test exhibited a correlation of 92.6% with bacterial culture.

Clinical Performance Comparing *C. DIFF QUIK CHEK COMPLETE™* Test to Bacterial Culture

n= 1126	Bacterial Culture positive	Bacterial Culture negative
***C. DIFF QUIK CHEK COMPLETE™* Antigen Line Positive**	201	62
***C. DIFF QUIK CHEK COMPLETE™* Antigen Line Negative**	21	842

		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

Twenty-nine of the 62 false positive samples were positive by the *C. DIFF CHEK™ - 60* ELISA, and were considered true positives. Thirteen of the 21 false negative samples were negative by the ELISA, and were considered true negatives.

Comparison of the GDH antigen portion to tissue culture assay

The following table shows a comparison of the GDH antigen portion of the *C. DIFF QUIK CHEK COMPLETE™* test versus tissue culture assay. The protocols are presented in the Appendices. The results show that the *C. DIFF QUIK CHEK COMPLETE™* test detected 98.7% of the tissue culture-positive samples.

Clinical Performance Comparing *C. DIFF QUIK CHEK COMPLETE™* Test to Tissue Culture Assay

n= 1126	Tissue Culture positive	Tissue Culture negative
***C. DIFF QUIK CHEK COMPLETE™* Antigen Line Positive**	154	109
***C. DIFF QUIK CHEK COMPLETE™* Antigen Line Negative**	2	861

		95% Confidence Limits
Percent Positive Agreement	98.7%	95.0 – 99.8
Percent Negative Agreement	88.8%	86.6 – 90.6
Overall Percent Agreement	90.1%	89.0 – 91.1

Analytical Sensitivity

The cutoff for the assay was established at a concentration of 0.8 ng/mL for Glutamate Dehydrogenase.

Summary of Performance Data
Clinical Accuracy
For Toxins A and B

The following tables show a summary of the clinical performance of the toxins A and B portion of the *C. DIFF QUIK CHEK COMPLETE*™ test. Results from all 3 clinical sites are included in the summary. Results from the *C. DIFF QUIK CHEK COMPLETE*™ were compared to tissue culture assay and discrepant results were analyzed by either the *C. DIFFICILE TOX A/B II*™ test or a second commercially available Toxin A/B test. The results show that the *C. DIFF QUIK CHEK COMPLETE*™ test exhibited a sensitivity and specificity of 87.8% and 99.4%, respectively, compared to the tissue culture assay. The predictive positive and negative values were 95.8% and 98.1%, respectively, and the correlation was 97.8%.

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

n= 1126	Tissue Culture positive	Tissue Culture negative
***C. DIFF QUIK CHEK COMPLETE*™ Toxin Line Positive**	137	6
***C. DIFF QUIK CHEK COMPLETE*™ Toxin Line Negative**	19	964

		95% Confidence Limits
Sensitivity	87.8%	81.4 – 92.3
Specificity	99.4%	98.6 – 99.7
Predictive Positive Value	95.8%	90.7 – 98.3
Predictive Negative Value	98.1%	96.9 – 98.8
Correlation	97.8%	97.6 – 98.0

Of the 6 tissue culture-negative/*C. DIFF QUIK CHEK COMPLETE*™-positive samples, 5 were positive in the *C. DIFFICILE TOX A/B II*™ test. Of the 19 specimens that were tissue culture-positive/*C. DIFF QUIK CHEK COMPLETE*™-negative, 12 were negative in the *C. DIFFICILE TOX A/B II*™ test or a second commercially available Toxin A&B test.

Analytical Sensitivity
The cutoff for the assay was established at concentrations of 0.63 ng/mL for toxin A and 0.16 ng/mL for toxin B.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

MAR 2 6 2009

Mr. Charles Pennington, MS
Director of Product Development
Techlab, Inc.
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Re: K082499
Trade/Device Name: C. DIFF QUIK CHEK COMPLETE™
Regulation Number: 21 CFR 866.2660
Regulation Name: Microorganism differentiation and identification device
Regulatory Class: I
Product Code: LLH
Dated: November 5, 2008
Received: February 26, 2009

Dear Mr. Pennington:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at 240-276-0450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Sally A. Hojvat, M.Sc., Ph.D.
Director
Division of Microbiology Devices
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

2. INDICATIONS FOR USE

510(k) Number (if known): K082499

Device Name: *C. DIFF QUIK CHEK COMPLETE™*

Indications For Use:

The *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.
FOR *IN VITRO* DIAGNOSTIC USE.

Prescription Use ___√____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

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Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

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