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K050891

7. 510(k) SUMMARY

Contact Information

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Product and Trade Name *TOX A/B QUIK CHEK*™

Classification 21 CFR 866.2660

Predicate Devices

- *C. DIFFICILE TOX-B TEST* (K935296) - TECHLAB, Inc., Blacksburg, VA
- *C. difficile* toxin/antitoxin (K923463) - TECHLAB, Inc., Blacksburg, VA
- *C. DIFFICILE TOX A/B II™* (K003306 and K030404) - TECHLAB, Inc., Blacksburg, VA
- Premier™ Toxins A&B (K993914) - Meridian Bioscience, Inc., Cincinnati, OH
- ProSpecT® Clostridium difficile Toxin A/B (K033479) - Remel, Lenexa, KS
- Immuno*Card*® Toxins A&B (K041003) - Meridian Bioscience, Inc., Cincinnati, OH
- Xpect™ Clostridium difficile Toxin A/B (K041951) - Remel Inc., Lenexa, KS

Intended Use

The *TOX A/B QUIK CHEK™* test is a rapid immunoassay for detecting *Clostridium difficile* 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 and results should be considered in conjunction with the patient history.

Device Description

The *TOX A/B QUIK CHEK™* test uses antibodies specific for toxins A and B of *C. difficile*. The device contains a Reaction Window with two lines of immobilized antibodies. The test line ("T") contains antibodies against *C. difficile* toxins A and B. The other, representing a control line ("C"), contains anti-IgG antibodies. The *Conjugate* consists of antibodies to toxins A and 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 toxin A and toxin B in the sample bind to anti-toxin antibody-peroxidase conjugate. The toxin-antibody complexes migrate through a filter pad to a membrane where they are captured by the immobilized anti-toxin antibodies in the line. The

Reaction Well is subsequently washed with *Wash Buffer*, followed by the addition of *Substrate*. After up to a 10 minute incubation, the "T" 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 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

Characteristics	510(k) Numbers	Intended Use	Format	Materials	Target Population
TOX A/B QUIK CHEK™ test	Subject to this 510(k)	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
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 KK030404	Detection of *C. difficile* toxin in fecal specimens	Microtiter 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	Microtiter 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	Microtiter 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

Summary of Performance Data

Clinical Accuracy

The tables below show a summary of the clinical performance of the *TOX A/B QUIK CHEK™* test. Results from 5 studies (2 in-house studies and 3 on-site studies) are included in the summary. Results from the *TOX A/B QUIK CHEK™* were compared to tissue culture assay. The *TOX A/B QUIK CHEK™* test exhibited a sensitivity and specificity of 90.2% and 99.7%, respectively. The predictive positive and negative values were 98.6% and 97.9%, respectively, and the correlation was 98.0%.

Summary of clinical performance comparing the *TOX A/B QUIK CHEK™* test versus tissue culture assay.

n=842	Tiss Cult pos	Tiss Cult neg
TOX A/B QUIK CHEK™ pos	138	2
TOX A/B QUIK CHEK™ neg	15	687

		95% CI
Sensitivity	90.2	84.1 - 94.2
Specificity	99.7	98.8 - 99.9
Predictive Positive Value	98.6	94.4 - 99.8
Predictive Negative Value	97.9	96.4 - 98.7
Correlation	98.0	97.8 - 98.2

Of the 2 tissue culture-negative/*TOX A/B QUIK CHEK™*-positive samples, 1 was negative in the *TOX A/B II™* test. Of the 15 specimens that were tissue culture-positive/*TOX A/B QUIK CHEK™*-negative, 12 were negative in a commercial A+B ELISA.

Analytical Sensitivity

The test was consistently positive at a concentration of 0.63 ng/mL for toxin A and 1.25 ng/mL for toxin B.

Cross-Reactivity

Strains of *C. difficile* that produce toxins A and B, or only toxin B, were demonstrated to react in the *TOX A/B QUIK CHEK™*. The specificity of the *TOX A/B QUIK CHEK™* test was evaluated by examining the reactivity of a wide range of common intestinal bacteria and intestinal pathogens in the assay. A summary of the results is shown below. The only non-*C. difficile* organism to react in the *TOX A/B QUIK CHEK™* test was *C. sordellii* VPI 9048, which produces toxin HT (hemorrhagic toxin) and toxin LT (lethal toxin) that are homologous to toxins A and B, respectively. All of the other organisms tested were negative in the *TOX A/B QUIK CHEK™*.

Bacterium	Strain	Reaction with *C. difficile* negative stool	Reaction with *C. difficile* positive stool
Aeromonas hydrophila	ATCC 7965	-	+
Bacillus cereus	ATCC 14579	-	+
Bacillus subtilis	ATCC 6051	-	+
Bacteroides fragilis	VPI 13785	-	+
Campylobacter coli	ATCC 49941	-	+
Campylobacter fetus	ATCC 25936	-	+
Campylobacter jejuni	ATCC 29428	-	+
Candida albicans	ATCC 10231	-	+
Clostridium bifermentans	VPI 2012	-	+
Clostridium butyricum	VPI 8260	-	+
Clostridium perfringens, types A	VPI 3624	-	+
Clostridium septicum	VPI 1524	-	+
Clostridium sordellii	VPI 9048	+	+
Clostridium sordellii	VPI 7319	-	+
Clostridium sporogenes	VPI 9743	-	+
Enterococcus faecalis	ATCC 19433	-	+
Escherichia coli EIEC	SD67	-	+
Escherichia coli	ATCC 25922	-	+
Escherichia coli O157 H7	B1409	-	+
Escherichia coli ETEC	E 2348169	-	+
Klebsiella pneumoniae	ATCC 9997	-	+
Peptostreptococcus anaerobius	ATCC 27337	-	+
Proteus vulgaris	ATCC 6380	-	+
Pseudomonas aeruginosa	ATCC 9027	-	+
Salmonella typhimurium	ATCC 14029	-	+
Shigella dysenteriae	ATCC 12022	-	+
Shigella flexneri	ATCC 12122	-	+
Shigella sonnei	ATCC 11060	-	+
Staphylococcus aureus	ATCC 6358	-	+

Bacterium	Strain	Reaction with *C. difficile* negative stool	Reaction with *C. difficile* positive stool
Staphylococcus aureus (Cowans)	ATCC 12598	-	+
Staphylococcus epidermidis	VPI 13140	-	+
Vibrio parahaemolyticus	ATCC 17802	-	+
Yersinia enterocolitica	ATCC 9610	-	+

Virus	ATCC#	Reaction with *C. difficile* negative stool	Reaction with *C. difficile* positive stool
Adenovirus type 1	VR-1	-	+
Adenovirus type 2	VR-846	-	+
Adenovirus type 3	VR-3	-	+
Adenovirus type 5	VR-5	-	+
Adenovirus type 40	VR-931	-	+
Adenovirus type 41	VR-930	-	+
Human coronavirus	VR-740	-	+
Coxsackievirus B2	VR-29	-	+
Coxsackievirus B3	VR-30	-	+
Coxsackievirus B4	VR-184	-	+
Coxsackievirus B5	VR-185	-	+
Echovirus 9	VR-1050	-	+
Echovirus 11	VR-1052	-	+
Echovirus 18	VR-48	-	+
Echovirus 22	VR-1063	-	+
Echovirus 33	VR-582	-	+
Enterovirus type 68	VR-1076	-	+
Enterovirus type 69	VR-1077	-	+
Enterovirus type 70	VR-836	-	+
Enterovirus type 71	VR-784	-	+

Interfering Substances

The following substances had no effect on test results, either with *C. difficile*-negative or *C. difficile*-positive specimens, when present in the stool in the concentrations indicated in the table.

Substance	Concentration	Reaction with *C. difficile* negative stool	Reaction with *C. difficile* positive stool
Hog gastric mucin	3.5% w/v	-	+
Human blood (O, Rh-)	40% v/v	-	+
Barium sulfate	5% w/v	-	+
Imodium®	5% w/v	-	+
Kaopectate®	5 mg/ml	-	+
Pepto-Bismol®	5% w/v	-	+
Steric/palmitic acid	40% w/v	-	+
Metronidazole	0.25% w/v	-	+
Vancomycin	0.25% w/v	-	+

Reproducibility

The reproducibility of the *TOX A/B QUIK CHEK™* test was determined using known positive (n=6) and negative (n=2) fecal specimens that were coded and sorted to prevent their identification during testing. Testing was performed on-site at 3 laboratories, which tested the samples on 3 days. The samples produced the expected results 100% of the time.

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Food and Drug Administration
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JUL 25 2005

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Re: k050891
Trade/Device Name: TOX A/B QUICK CHECK™
Regulation Number: 21 CFR 866.2660
Regulation Name: Microorganism differentiation and identification device
Regulatory Class: Class I
Product Code: LLH
Dated: July 5, 2005
Received: July 8, 2005

Dear Dr. Lyerly:

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 information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (240)276-0484. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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 (301) 443-6597 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

REVISED

Indications for Use

510(k) Number (if known): K050891

Device Name: *TOX A/B QUIK CHEK™*

Indications For Use:

The *TOX A/B QUIK CHEK™* test is a rapid immunoassay for detecting *Clostridium difficile* 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 and results should be considered in conjunction with the patient history. FOR *IN VITRO* DIAGNOSTIC USE.

Prescription Use X AND/OR Over-The-Counter Use

(Part 21 CFR 801 Subpart D) (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)

Freddie L. Poole

Division Sign-Off

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Office of In Vitro Diagnostic Device Evaluation and Safety

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