K955859

510(k) Summary APR 18 1996

Meridian Diagnostics, Inc.
Cincinnati, Ohio 45244

APPENDIX A - 510(k) Summary

E. Identification Information

1) **Submitter's Information:**

a) **Submitter's Name and Address:**

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c) **Contact Person:** Allen D. Nickol, PhD
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d) **Date Summary Prepared:** December 22, 1995

2) **Name of Device: ImmunoCard Toxin A.** The **ImmunoCard Toxin A** enzyme immunoassay (EIA) is a rapid in vitro qualitative procedure for detecting Clostridium difficile toxin A in human stool. The test can be used to aid in the diagnosis of C. difficile-associated disease. The test may also be used to determine the production of toxin A by C. difficile in BHI broth culture. Classification Name unknown.

3) **Predicate Equivalent Device:** Tissue culture cytotoxin assay with neutralization using specific anti-toxin.

4) **Description of Device:** The **ImmunoCard Toxin A** assay system is a card based EIA for toxin A of C. difficile. Each kit contains the following components:

a) Toxin A ImmunoCards (50)
b) Positive Control (0.5ml)
c) Enzyme Conjugate (7.5ml)
d) Sample Diluent (10.0ml)
e) Wash Reagent (28ml)
f) Substrate Reagent (13ml)
g) Transfer Pipets (50)

In brief, the assay is performed by preparing a 1/15 dilution of stool in a mixture of Sample Diluent and Enzyme Conjugate. Using a transfer pipet, 150µl of diluted specimen are then added to each of the lower (sample application) ports on an ImmunoCard. The sample is allowed to enter the card for 5 minutes. Three drops of Wash Reagent are added to each of the upper (Reaction) ports and

allowed to enter the card. Three drops of Substrate Reagent are then added and the card is viewed for visible blue color development after 5 minutes.

5) **Intended Use:** The **ImmunoCard Toxin A** enzyme immunoassay (EIA) is a rapid in vitro qualitative procedure for detecting Clostridium difficile toxin A in human stool. The test can be used to aid in the diagnosis of C. difficile-associated disease. The test may also be used to determine the production of toxin A by C. difficile in BHI broth culture.

6) **Comparison with Predicate Devices:** The following comparison of the use, technology, function and performance supports the Statement of Equivalence between the **ImmunoCard Toxin A** test and cytotoxin testing.

a) Both assays detect toxins of C. difficile in patient stools. The **ImmunoCard Toxin A** test detects enterotoxin (toxin A), the etiologically important toxin. The cytotoxin assay detects toxin B, which is associated with disease through coproduction with toxin A.

b) Both assays are in vitro immunoassays. The **ImmunoCard Toxin A** test is an EIA, while the cytotoxin assay is an antibody-dependent toxin neutralization bioassay.

c) Both tests are performed directly on stool extracts. The **ImmunoCard Toxin A** test utilizes a Sample Diluent and Enzyme Conjugate, while the cytotoxin assay requires sample dilution, centrifugation and filtration.

d) Both assays yield qualitative results (i.e. positive or negative). The cytotoxin assay can be performed using higher than standard (1/40) dilutions, although the diagnostic significance of this has yet to be determined.

e) Equivalent relative performance was recorded relative sensitivity 82.7%, relative specificity 98.2%, relative agreement 96.2%) when comparing the **ImmunoCard Toxin A** and cytotoxin tests. When **ImmunoCard Toxin A** results were compared with concordant result of 3 reference methods (Toxin A EIA, cytotoxin and toxigenic culture), sensitivity, specificity and agreement were 85.2%, 97.5% and 96.0%.

f) These clinical data demonstrate the correlation between

the two methods, supporting the **ImmunoCard Toxin A** EIA as being substantially equivalent to the reference cytotoxin method.

F. Additional Information/Nonclinical Test Results:

1) Sensitivity Limits: The sensitivity of the **ImmunoCard Toxin A** is approximately 32 pg of toxin A. Allowing for the 1/15 dilution of sample and 150μl assay volume, this equates to 3.2ng toxin A/ml of stool as the **ImmunoCard Toxin A** limit of detection.

2) Reproducibility: Reproducibility of the **ImmunoCard Toxin A** test was evaluated by running strong positive, weak positive, and negative stools. Ten specimens were tested in triplicate on each of 3 different days at 3 different locations. No incorrect results were obtained with any test or procedural control.

3) Fresh versus Frozen Stools: The data indicated toxin A is stable in stool for at least 3 days when stored at 4°C. If specimen cannot be tested within this period, freezing the specimen is recommended (≤ -20°C) and does not appreciably alter performance.