

Meridian Diagnostics, Inc.
Cincinnati, OH 45244

K961508
Jan. 21, 1997
510(k) Notification
ImmunoCard H. pylori

APPENDIX A - 510(k) SUMMARY

A. Identification Information

1. Submitter's Information:

a. Submitter's Name and Address:

Meridian Diagnostics, Inc.
3471 River Hills Drive
Cincinnati, OH 45244

b. Phone Number: 1-800-543-1980

c. Contact Person: Allen D. Nickol, Ph.D. Director Scientific and Regulatory Affairs

d. Date Summary Prepared: March 19, 1996

2. Name of Device: ImmunoCard H. pylori Classification Name: Campylobacter pylori (LYR)

3. Predicate Equivalent Device: ImmunoCard Helicobacter pylori

4. Description of Device: The ImmunoCard H. pylori assay system is a membrane based EIA for detecting IgG to H. pylori in human serum and plasma. Each kit contains the following components:

- a. H. pylori Test Cards (30)
- b. Enzyme Conjugate (5ml)
- c. Wash Buffer (15ml)
- d. Substrate Reagent (15ml)
- e. Positive Control (2ml)
- f. Negative Control (2ml)
- g. Whole Blood Sample Diluent (6.5ml)
- h. Heparinized Capillary Tubes (30)
- i. Transfer Pipets (30)

Serum and Plasma Assay

Two drops of serum or plasma are added to each of the two sample ports. The serum migrates into the sample wicks and up towards the reaction ports and beyond. After one minute, two drops of conjugate (mouse monoclonal antibody to human IgG, conjugated with alkaline phosphatase) are added to each of the two reaction ports.

Whole Blood Assay

Four drops of Whole Blood Sample Diluent, then two drops of whole blood are added to a specimen cup. Two drops of the diluted whole blood are added to each of the two sample ports. The blood migrates into the sample wicks and up towards the reaction ports and beyond. After three minutes, two drops of conjugate (mouse monoclonal antibody to human IgG, conjugated with alkaline phosphatase) are added to each of the two reaction ports.

Both Assays

After conjugate absorption, two drops of wash buffer are added to the reaction ports, followed by two drops of substrate (BCIP). Reaction ports are observed for the development of any blue color after five minutes. The development of blue color in the right hand port indicates a positive test result for IgG to H. pylori. A lack of blue color in the right hand port indicates a negative result. The left reaction port, containing immobilized human IgG, serves as a procedural control. Failure of the left hand port to develop a blue color indicates an invalid test.

5. **Intended Use:** The ImmunoCard H. pylori enzyme immunoassay (EIA) is an in vitro qualitative procedure for the detection of IgG to Helicobacter pylori in human serum, plasma and whole blood. Test results are intended to aid in the diagnosis of H. pylori infection. ImmunoCard H. pylori may be performed by clinical laboratories or in physician's offices.

6. **Comparison with Predicate Devices:** The following comparison of performance supports the Statement of Equivalence between the ImmunoCard H. pylori and ImmunoCard Helicobacter pylori Whole Blood Assay.

| | ImmunoCard <u>H. pylori</u> | |
|--|-----------------------------|----------|
| ImmunoCard <u>H. pylori</u> Whole Blood | Positive | Negative |
| Positive | 30 | 0 |
| Negative | 1 | 77 |

n = 108

Relative Agreement = 99.1 ± 1.8%* (107/108)

*95% confidence intervals.

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A. **Additional Information/Nonclinical Test Results:**

1. **Reproducibility:**

- a. Intra-assay and Inter-assay reproducibility of the positive control, negative control, positive specimens and negative specimens was 100%.

2. **Sample Storage:**

IgG to H. pylori is stable in whole blood for at least three days when stored at 4°C.

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