K953839

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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, Ohio 45244

   b. **Phone Number:** 1-513-271-3700

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

   d. **Date Summary Prepared:** August 11, 1995

2. **Name of Device:** Premier HSV Plus

   a. **Classification Name:** Enzyme Linked Immunosorbent Assay, Herpes Simplex Virus (83LGC)

3. **Predicate Equivalent Device:** Premier HSV

4. **Description of Device:** The Premier HSV Plus assay system is a microwell-based sandwich EIA for the detection of herpes simplex virus. Each kit contains the following components:

a.	Capture Antibody-coated microwells	1 x 96
b.	Positive Control	6.5ml
c.	Negative Control	6.5ml
d.	Extraction Buffer	15ml
e.	Enzyme Conjugate	10ml
f.	20X Wash Buffer	50ml
g.	Substrate	10ml
h.	Stop Solution	10ml
i.	Transfer Pipet	96
j.	Microwell Strip Holder	1X
k.	Microwell Strip Sealer	2X

The assay is performed by adding two free drops (or 50μl) of Extraction Buffer to all wells. Then add four free drops (200μl) each of positive and negative control to the control wells, or 200μl of sample into appropriate wells and incubate 90 minutes at 37-39°C. Wash 5X with wash buffer. Add two free drops (100μl) of enzyme conjugate to each well, cover and incubate 30 minutes at 37-39°C. Then wash 5X with a five minute soak. Add two free drops (100μl) of substrate to all wells and incubate ten minutes at room temperature. Add two free drops (50μl) of Stop Solution to each well. Wait two minutes and read at 450/630nm.

5. **Intended Use:** The Premier HSV is a qualitative enzyme immunoassay designed for detection of herpes simplex virus (HSV). The test is intended to be used for direct detection from genital or other skin vesicles/ulcerated lesions or asymptomatic genital specimens to rapidly confirm the presence of HSV. The test can also be used in conjunction with cell cultures inoculated with these specimens.

6. **Comparison with Predicate Devices:**

   a. Both assays employ enzyme immunoassay technology

   b. Both methodologies are specific for detection of HSV antigens.

7. **Clinical Trial Results:** Comparison of the performance of Premier HSV Plus Direct EIA and Spin-Amp EIA procedure to culture with FA confirmation of positives

Direct EIA vs Culture with FA Confirmation

Specimen Type	N	Relative Sensitivity		Relative Sensitivity	
		Initial	Resolved	Initial	Resolved
Genital Symptomatic	393	88.9% (152/171)	93.1% (161/173)	98.2% (218/222)	100% (220/220)
Genital Asymptomatic	78	80% (4/5)	83.3% (5/6)	98.6% (72/73)	100% (72/72)
Oral	42	92.9% (13/14)	92.9% (13/14)	100% (28/28)	100% (28/28)
Others*	43	92.3% (12/13)	92.3% (12/13)	100% (30/30)	100% (30/30)
Total	556	89.2% (181/203)	92.7% (191/206)	98.6% (348/353)	100% (350/350)

*Skin lesion specimens other than genital, oral, and ocular.

Spin-Amp EIA vs Culture with FA Confirmation

Specimen Type	N	Relative Sensitivity		Relative Sensitivity	
		Initial	Resolved	Initial	Resolved
Genital Symptomatic	393	98.3% (168/171)	99.4% (173/174)	97.3% (216/222)	99.5% (218/219)
Genital Asymptomatic	78	100% (5/5)	100% (6/6)	98.6% (72/73)	100% (72/72)
Oral	42	92.9% (13/14)	92.9% (13/14)	100% (28/28)	100% (28/28)
Others*	43	100% (13/13)	100% (13/13)	100% (30/30)	100% (30/30)
Total	556	98.0% (199/203)	99.0% (205/207)	98.0% (346/353)	99.7% (348/349)

B. Additional Information/Nonclinical Test Results

1. Reproducibility

a. Intra-assay variability

Intra-assay Variation

Sample	Mean O.D. Range	C.V. Range
HSV-1 (H)	1.01 - 1.55	1.8 - 17.4%
HSV-1 (M)	0.52 - 0.92	1.5 - 13.5%
HSV-1 (L)	0.33 - 0.44	3.9 - 13.4%
HSV-2 (H)	1.36 - 1.61	1.4 - 13.9%
HSV-2 (M)	0.33 - 0.48	1.3 - 12.4%
HSV-2 (L)	0.17 - 0.33	1.9 - 14.1%
Negative Control	0.08 - 0.12	2.4 - 18.7%

b. Inter-assay variability

Inter-Assay Variation

Sample	Mean O.D. Range	C.V. Range
HSV-1 (H)	1.26 - 1.48	8.8 - 29.9%
HSV-1 (M)	0.54 - 0.62	0.8 - 21.9%
HSV-1 (L)	0.37 - 0.44	14.7 - 22.0%
HSV-2 (H)	1.36 - 1.46	0.8 - 16.0%
HSV-2 (M)	0.39 - 0.40	18.6 - 32.7%
HSV-2 (L)	0.21 - 0.29	6.9 - 18.4%
Negative Control	0.09 - 0.10	12.0 - 29.5%

2. **Sensitivity Limits:** The sensitivity of Premier HSV Plus for HSV-1 and HSV-2 is 10 $TCID_{50}$ units and 30 $TCID_{50}$ units respectively.