510(k) SUMMARY

K111951

SEP 27 2011

1.0 Submitter

Date of Summary: September 24, 2011

Product Name: IsoAmp® HSV Assay

Sponsor:
BioHelix Corporation
500 Cummings Center
Suite 5550
Beverly, MA 01915

Correspondent :
MDC Associates, LLC
Fran White, Regulatory Consultant
180 Cabot Street
Beverly, MA 01915

2.0 Device Identification

Trade or Proprietary Name:	IsoAmp® HSV Assay
Common or Usual Name:	Herpes simplex virus Assay
Product Code:	OQO
Regulation Section:	21 CFR 866.3305
Product Classification:	Class II

3.0 Substantial Equivalency

IsoAmp® HSV Assay is substantially equivalent to the EraGen Biosciences MultiCode®-RTx Herpes Simplex Virus 1 & 2 Kit (K100336). The table below identifies the characteristics of BioHelix Corporation's IsoAmp® HSV Assay (K111951) and the EraGen Biosciences MultiCode®-RTx Herpes Simplex Virus 1 & 2 Kit (Predicate Device).

Comparison of New Device with Predicate Device

Features	BioHelix Corporation IsoAmp® HSV Assay (New Device)	EraGen Bioscience Multicode® RTx Herpes Simplex Virus 1 & 2 Kit (Predicate Device)
	K111951	K100336
	SIMILARITIES	
Intended use	The IsoAmp® HSV Assay is an *in vitro* diagnostic test for the direct, qualitative detection of herpes simplex virus (HSV-1 & HSV-2) DNA in male and female genital and oral lesions. The test is intended for use as an aid in diagnosis of HSV infection in symptomatic patients. ***Warning*: The IsoAmp® HSV Assay is not FDA cleared for use with cerebrospinal fluid (CSF). The assay does not provide specific typing information to differentiate HSV-1 and HSV-2. The assay is not intended to be used for prenatal screening.**	The MultiCode®-RTx HSV-1&2 Kit is a polymerase chain reaction (PCR) –based qualitative *in vitro* diagnostic test for the detection and typing of herpes simplex virus (HSV-1&2 DNA in vaginal lesions. It is indicated for use in the detection and typing of HSV-1 or HSV-2 in vaginal lesion swab specimens from symptomatic female patients as an aid in the diagnosis of genital herpes infection. ***Warning:* The device is no FDA cleared for the use with cerebral spinal fluid (CSF) or any lesions other than vaginal. This assay is not intended to be used for male penile specimens, for prenatal screening, or for females under the age of 18 years.**
Assay Results	Qualitative	Qualitative
Analysis Software Provided	No	Yes
Printed Results Report Provided	No	No
Detection of HSV-1 and HSV-2	Yes	Yes
	DIFFERENCES	
Methodology	HDA (Helicase-Dependent Amplification)	Real-Time PCR
Typing of HSV-1 and HSV-2	No	Yes
Packaging	The product is supplied as two (2) separate labeled boxes.	The product is supplied in labeled, sterile tubes. The outer container is a labeled box.
Kit Reagent Storage Conditions	AKRC: ≤-15°C NKC: 15-30°C	-15°C to -30°C

4.0 Product Description

The IsoAmp® HSV Assay consists of three major steps: 1) specimen preparation: 2) isothermal Helicase-Dependent Amplification (HDA) of the HSV glycoprotein B (gB) gene using biotinylated primers; and 3) detection of the amplified DNA by a target-specific hybridization probe via a colorimetric reaction on a lateral-flow strip which is embedded in a self-contained disposable cassette to prevent amplicon contamination.

Specimen preparation includes a simple dilution step in which specimens in viral transport medium are diluted 40-fold in dilution buffer. The diluted samples are mixed with HDA reagents. Incubation at 64°C results in the release of the HSV DNA and subsequent isothermal amplification of the target sequence. A competitive internal control (IC) is included in the Amplification Reagents to monitor inhibitory substances in negative samples, reagent failure or device failure.

After incubation for one hour, the amplified DNA is detected by two detection probes, one labeled with fluorescein isothiocyanate (FITC) for hybridizing to the HSV target and the other labeled with digoxigenin (DIG) for binding to the IC target. The hybrid of FITC-labeled probe and HSV amplicon is captured at the Test Line (T-Line) on the lateral-flow strip by anti-FITC antibodies, while the DIG-labeled IC amplicon is captured at the Control Line (C-Line) on the strip by anti-DIG antibodies. The biotin label in each amplicon captures the streptavidin-conjugated color particles for visualization and the test result is shown as colored lines that are visually read.

The self-contained Type II BESt™ cassettes contain lateral-flow DNA detection strips coated with anti-FITC antibodies and anti-DIG antibodies that serve as T line and C line respectively in the assay. A positive result (detection of HSV DNA) is reported when the T line is visible through the detection window of the cassette. A negative result (no detection of HSV DNA) is reported when only the C line is displayed. The assay result is regarded as invalid when both the T line and C line are not present and the assay should be repeated.

5.0 Indications for Use and Intended Use

The IsoAmp® HSV Assay is an *in vitro* diagnostic test for the direct, qualitative detection of herpes simplex virus (HSV-1 & HSV-2) DNA in male and female genital and oral lesions. The test is intended for use as an aid in diagnosis of HSV infection in symptomatic patients.

***Warning*: The IsoAmp® HSV Assay is not FDA cleared for use with cerebrospinal fluid (CSF). The assay does not provide specific typing information to differentiate HSV-1 and HSV-2. The assay is not intended to be used for prenatal screening.**

6.0 Analytical Performance

I. Precision/Reproducibility:

The Precision/Reproducibility of the IsoAmp® HSV Assay was evaluated at three (3) test sites. A panel of seven (7) members was prepared containing one negative control sample (HSV negative pooled swab specimens) and six simulated HSV-1 and HSV-2 samples that included High Negative (below the assay limit of detection), Low Positive (near the assay limit of detection) and Moderate Positive (three times the assay limit of detection) samples. The panel (which included one replicate of each panel member), along with external HSV-1 and HSV-2 positive and negative controls, was tested at each site for five (5) days

by two operators with each operator running the panel two times a day using a single lot of the IsoAmp® HSV Assay. One (1) site tested the panel using three (3) lots. Results of the Precision/Reproducibility study for the IsoAmp® HSV at three sites are presented in the table below.

Overall Reproducibility Study

Category	LOT						Overall Percent Agreement		95% Confidence Interval
	Site #1*		Site #2		Site #3				
	Percent Agreement		Percent Agreement		Percent Agreement				
HSV-1 High Negative	13/60	22%	13/20	65%	6/20	30%	32/100	32%	24% - 42%
HSV-1 Low Positive	60/60	100%	19/20	95%	20/20	100%	99/100	99%	94% - 100%
HSV-1 Moderate Positive	60/60	100%	20/20	100%	20/20	100%	100/100	100%	96% - 100%
HSV-2 High Negative	19/60	32%	7/20	35%	6/20	30%	32/100	32%	24% - 42%
HSV-2 Low Positive	60/60	100%	18/20	90%	18/20	89%	96/100	96%	90% - 98%
HSV-2 Moderate Positive	60/60	100%	20/20	100%	20/20	100%	100/100	100%	96% - 100%
Negative[1]	60/60	100%	20/20	100%	19/20	95%	99/100	99%	96% - 100%
HSV-1 Positive Control	60/60	100%	20/20	100%	20/20	100%	100/100	100%	96% - 100%
HSV-2 Positive Control	60/60	100%	20/20	100%	20/20	100%	100/100	100%	96% - 100%
Assay Negative Control[2]	60/60	100%	20/20	100%	20/20	100%	100/100	100%	96% - 100%
	*Site#1 tested two additional lots								

II. Linearity/Assay Reportable Range:
Not Applicable

III. Level of Detection (LoD)
A Limit of Detection (LoD) study was performed to determine the analytical sensitivity of the IsoAmp HSV Assay using two representative strains of HSV-1 and two representative strains of HSV-2. Quantified ($TCID_{50}$/mL) cultures of the HSV-1 and HSV-2 strains were serially diluted to five (5) concentrations in HSV-negative matrix pools and tested in replicates of ten (10) on three (3)

[1] Negative pooled serum control
[2] Remel M4 transport media

reagent lots. The observed LoD of a HSV strain was determined as the lowest concentration level that had a positivity rate of ≥95%. Since two (2) representative strains of HSV-1 and HSV-2 were used in the study, the higher LoD value was defined as the observed LoD for HSV-1 and HSV-2 respectively. Since the IsoAmp® HSV Assay does not differentiate viral types, the final assay LoD is defined as the higher of the HSV-1 and HSV-2 concentrations where 95% positivity was observed.

In addition, LoD confirmation studies were conducted to confirm the observed LoD for HSV-1 and HSV-2. The first confirmatory study included testing the four (4) representative HSV-1 and HSV-2 strains 20 times each at the corresponding observed LoD. Each strain was tested by three (3) reagent lots, and all four strains showed a positivity rate of 100%. In addition, twenty (20) HSV-1 and 20 HSV-2 clinical isolates were cultured and quantified in $TCID_{50}$/mL. Each isolate was diluted to the corresponding LoD in HSV-negative matrix and tested in triplicate. IsoAmp® HSV Assay was able to detect all 20 HSV-1 and 20 HSV-2 clinical isolates.

a. HSV-1

The LoD for HSV-1 Strain 1 was determined to be 3.7×10^4 $TCID_{50}$/mL. At this concentration, 97% of samples were detected with a 95% Confidence Interval of 83.33% – 99.41%. The LoD for HSV-1 Strain 2 was determined to be 1.1×10^5 $TCID_{50}$/mL. At this concentration, 100% of samples were detected with a 95% Confidence Interval of 88.65% – 100%. Therefore, the LoD for HSV-1 is 1.1×10^5 $TCID_{50}$/mL.

Strain 1 ($TCID_{50}$/mL)	Positive/Total	Positivity Rate	95% CI	
3.3×10^5	30/30	100%	88.65%	100.00%
1.1×10^5	30/30	100%	88.65%	100.00%
3.7×10^4	29/30	97%	83.33%	99.41%
1.2×10^4	18/30	60%	42.32%	75.41%
4.1×10^3	10/30	33%	19.23%	51.22%
Strain 2 ($TCID_{50}$/mL)	Positive/Total	Positivity Rate	95% CI	
3.3×10^5	30/30	100%	88.65%	100.00%
1.1×10^5	30/30	100%	88.65%	100.00%
3.7×10^4	28/30	93%	78.68%	98.15%
1.2×10^4	19/30	63%	45.51%	78.13%
4.1×10^3	9/30	30%	16.66%	47.88%

b. HSV-2

The LoD for HSV-2 Strain 1 was determined to be 1.1×10^4 $TCID_{50}$/mL. At this concentration, 100% of samples were detected with a 95% Confidence Interval of 88.65% – 100%. The LoD for HSV-2 Strain 2 was

determined to be 3.7×10^3 $TCID_{50}$/mL. At this concentration, 100% of samples were detected with a 95% Confidence Interval of 88.30% – 100%. Therefore, the LoD for HSV-2 is 1.1×10^4 $TCID_{50}$/mL.

Strain 1 ($TCID_{50}$/mL)	Positive/Total	Positivity Rate	95% CI	
3.3×10^4	30/30	100%	88.65%	100.00%
1.1×10^4	30/30	100%	88.65%	100.00%
3.7×10^3	26/30	87%	70.32%	94.69%
1.2×10^3	14/30	47%	30.23%	63.86%
4.1×10^3	8/30	27%	14.18%	44.45%
Strain 2 ($TCID_{50}$/mL)	Positive/Total	Positivity Rate	95% CI	
3.3×10^4	30/30	100%	88.65%	100.00%
1.1×10^4	30/30	100%	88.65%	100.00%
3.7×10^3	29/29	100%	88.30%	100.00%
1.2×10^3	25/30	83%	66.44%	92.66%
4.1×10^2	8/30	27%	14.18%	44.45%

c. *Assay LoD*

Since the IsoAmp® HSV Assay does not differentiate viral types, the final assay LoD is defined as the higher of the HSV-1 and HSV-2 concentrations where 95% positivity was observed. The final assay LoD claim is 1.1×10^5 $TCID_{50}$/mL.

IV. Cross Reactivity Testing (Analytical Specificity)

A cross-reactivity study was performed to determine if any organisms which may present with the same clinical symptoms as HSV, which are associated with bacterial vaginosis or which are commonly found in the genital track and oral area could give positive results with the IsoAmp® HSV Assay. Forty-eight (48) specificity panel members including purified DNA and cultured organisms were tested with the IsoAmp® HSV assay in triplicate following instructions in the Package Insert. No cross-reactivity was observed with any panel member tested at clinically significant concentrations.

Organisms	Member Type (GD[1], QC[2], IHC[3])	Test Concentration
Acinetobacter calcoaceticus var. anitratus (ATCC 51432)	IHC	1.0×10^6 CFU/mL
Acinetobacter lwoffi (ATCC 17925)	IHC	1.0×10^7 CFU/mL
Adenovirus 2	QC	1.0×10^6 $TCID_{50}$/mL
Bacteroides fragilis	QC	1.0×10^7 CFU/mL
Candida albicans (ATCC 14053)	IHC	1.0×10^7 CFU/mL

[1] Genomic DNA
[2] Quantified Cultures
[3] In-House Culture

Organisms	Member Type (GD[1], QC[2], IHC[3])	Test Concentration
Candida glabrata	QC	1.0×10^7 CFU/mL
Candida guilliermondii	QC	1.0×10^7 CFU/mL
Candida krusei	QC	1.0×10^6 CFU/mL
Candida lusitaniae	QC	1.0×10^7 CFU/mL
Candida parapsilosis	QC	1.0×10^7 CFU/mL
Candida tropicalis	QC	1.0×10^7 CFU/mL
Chlamydia trachomatis LGV-II434	GD	1.0×10^7 cp/mL
Cytomegalovirus	QC	1.0×10^6 $TCID_{50}$/mL
Enterobacter cloacae (ATCC 13047)	IHC	1.0×10^7 CFU/mL
Enterovirus (Type 71)	QC	1.0×10^5 $TCID_{50}$/mL
Epstein-Barr Virus	GD	1.0×10^6 cp/mL
Escherichia coli (ATCC 25922)	IHC	1.0×10^7 CFU/mL
Fusobacterium nucleatum (ATCC 25586)	IHC	1.0×10^7 CFU/mL
Gardnerella vaginalis (ATCC 14018)	IHC	1.0×10^7 CFU/mL
Haemophilus ducreyi	QC	8.5×10^5 CFU/mL
Human Herpes 6 virus (Z29 strain)	QC	1.0×10^6 $TCID_{50}$/mL
Human Herpes 7 virus (SB strain)	QC	1.0×10^6 $TCID_{50}$/mL
Human papilloma virus 16 (HPV16)	GD	1.0×10^6 cp/mL
Human papilloma virus 18 (HPV18)	GD	1.0×10^5 cp/mL
Klebsiella pneumoniae	QC	1.0×10^7 CFU/mL
Lactobacillus acidophilus Z048	QC	1.0×10^7 CFU/mL
Mobiluncus curtisii V125 [DSM 2711]	QC	1.0×10^7 CFU/mL
Mobiluncus mulieris BV 64-5	QC	1.0×10^6 CFU/mL
Moraxella catarrhalis	QC	1.0×10^7 CFU/mL
Mycoplasma hominis (ATCC 23114)	IHC	1.0×10^7 CFU/mL
Neisseria gonorrhoeae (ATCC 21823)	IHC	1.0×10^7 CFU/mL
Neisseria meningitides	QC	1.0×10^7 CFU/mL
Prevotella melaninogenica	QC	1.0×10^7 CFU/mL
Rubella virus	QC	4.17×10^5 $TCID_{50}$/mL
Simian Virus type 40 (SV40)	QC	1.0×10^6 $TCID_{50}$/mL
Staphylococcus aureus MRSA (ATCC 33591)	IHC	1.0×10^7 CFU/mL
Staphylococcus aureus MSSA (ATCC 25923)	IHC	1.0×10^7 CFU/mL
Staphylococcus epidermidis MRSE (ATCC700566)	IHC	1.0×10^7 CFU/mL
Staphylococcus saprophyticus MRSE (ATCC 15305)	IHC	1.0×10^7 CFU/mL
Streptococcus mitis clinical isolate	QC	1.0×10^7 CFU/mL
Streptococcus mutans Z072	QC	1.0×10^6 CFU/mL

Organisms	Member Type (GD[1], QC[2], IHC[3])	Test Concentration
Streptococcus pneumoniae	QC	1.0 x 10^7 CFU/mL
Streptococcus pyogenes: (ATCC19615)	IHC	1.0 x 10^7 CFU/mL
Streptococcus salivarius (ATCC BAA-1024)	IHC	1.0 x 10^7 CFU/mL
Toxoplasma gondii	QC	6.6 x 10^6 CFU/mL
Treponema pallidum	QC	1.0 x 10^7 TP/mL
Trichomonas vaginalis	QC	1.0 x 10^6 CFU/mL
Varicella-Zoster Virus (VZV)	GD	1.0 x 10^6 cp/mL

V. Interfering Substances

Potentially interfering substances *i.e.* viral transport media, substances that might be present in clinical samples, and organisms/cross reactive panel members listed under cross reactivity were tested to confirm that they did not interfere with the performance of the IsoAmp® HSV Assay.

All interference testing was carried out in the presence of HSV-1 and HSV-2 at three times the observed LoD (3 x LoD). All test runs were conducted in triplicate. Controls were tested with each run.

a. Interfering Substances

Performance of the IsoAmp® HSV Assay was characterized in the presence of twenty-four (24) potentially interfering substances which could reasonably be expected to be present in genital and oral swab specimens. Interfering substances were tested at the highest ("worst case") concentration expected in clinical samples. The panel was also tested in triplicate in the absence of HSV to see if the potentially interfering substances interfere with the detection of the internal control. No interference was observed in the presence of the potential interfering substances tested.

Substances (active ingredients)	Calculated Concentration
Whole blood with EDTA	7% (v/v)
Female Urine	7% (v/v)
Male Urine	7% (v/v)
Acyclovir (Acycloguanosine) 10%	7 mg/mL
Albumin	3.3 mg/mL
Casein	7 mg/mL
K-Y Brand Jelly	7% (w/v)
Douche (Decyl Glucoside; Octoxynol-9)	7% (v/v)
Contraceptive Jelly	7% (w/v)
YeastGard (Phosphoricum Acidum 4X)	7% (w/v)
Monistat 1 (Miconazole Nitrate cream (2%))	7% (w/v)
Vagisil Crème (Benzocaine (20%), Resorcinol (3%))	7% (w/v)
Monistat 3 (Miconazole Nitrate Cream (4%))	7% (w/v)

Triconazole 1 (Tioconazole (300 mg) (6.5%))	7% (w/v)
Balneol Hygienic Cleansing Lotion	7% (w/v)
Clotrimazole 3 Vaginal Cream (Clotrimazole 100 mg (2%))	7% (w/v)
CVS Anti-Itch Cream (Benzocaine 5%; Benzalkonium Chloride 0.13%)	7% (w/v)
Listerine Antiseptic Mouth Wash	7% (v/v)
Abreva (Docosanol 10%)	7% (w/v)
Carmex Cold Sore Lip Balm (Menthol (0.7%), Camphor (1.7%), Phenol (0.4%))	7% (w/v)
Releev cold sore treatment (Benzalkonium Chloride (0.13%))	7% (w/v)
Lip clear Lysine+ (Zinc Oxide (1.2%))	7% (w/v)
Toothpaste	7% (w/v)
Buffy coat	7% (v/v)

b. Viral Transport Media

The performance of the IsoAmp® HSV Assay was assessed with Remel M4, Remel M5, Remel M4RT, Bartels VTM, and BD Universal Viral Transport (UVT). Each medium was tested after spiking with HSV-1 and HSV-2 strain to a final concentration of approximately 3 x LoD to determine if the viral transport media interferes with the detection of HSV targets in positive samples. The media were tested in the absence of HSV-1 and HSV-2 (medium only) to see if the viral transport media interferes with the detection of the internal control in negative samples. There was no interference observed with the Remel M4, Remel M4RT, Remel M5, Bartels VTM, and BD UVT media for the detection of HSV-1 and HSV- 2 target or the internal control. M4, M4RT, M5, Bartels VTM, and BD UVT did not interfere with the detection of HSV-1 and HSV-target or the internal control.

c. Cross-Reactivity Panel Members

The performance of the IsoAmp® HSV Assay was characterized by testing the organisms that were evaluated for analytical specificity and cross reactivity in the presence of HSV-1 and HSV-2 strains at 3xLoD separately to see if the presence of these organisms interferes with the detection of HSV target. Each panel member was tested in triplicate. None of the cross reactivity panel members interfered with the detection of HSV-1 and HSV-2 target.

VI. Carry-Over and Cross Contamination

Carry-over/Cross Contamination Study was done only with HSV-1 target since both HSV-1 and HSV-2 share a single set of primers and probes for target amplification and detection. The HSV-1 Strain 1 was used directly without dilution. Viral transport media was used as the negative sample. Ten (10) replicates of negative sample together with assay controls were run by two (2) operators to confirm that negative samples generate a negative result 100% of the time. Five (5) replicates of high-concentration positive and negative samples were tested in a series, alternating sample types. All results were

as expected. Negative samples tested were negative (10/10) and positive samples were positive (10/10).

VII. Assay Cut-Off:
Not Applicable

7.0 Clinical Performance

The performance of the IsoAmp® HSV Assay was evaluated at five geographically diverse locations within the United States from 2010 - 2011. A total of nine hundred and ninety-four (994) swab samples obtained from male and female genital and oral lesions were collected in Viral Transport Media (Remel M4, Remel M4RT, BD Universal Viral Transport and Bartels VTM) from the patient population ranging from <1 year to 92 years, and evaluated. Of the 994 specimens, 962 prospective samples and 32 retrospective samples were tested. Of the 962 prospective samples, 803 genital samples and 159 oral samples were tested. Of the 32 retrospective samples, 15 genital and 17 oral samples were tested at a single study site. Genital swab specimens were collected from vaginal, labial, penile and rectal lesions. Oral swab specimens were collected from lips, gums, and mouth.

The performance of the IsoAmp® HSV Assay was compared with a gold standard/reference method *i.e.*, Cell Culture based ELVIS® HSV ID/Typing Test System using an enzyme linked virus inducible system.

I. Prospective Sample Data

a. Genital Samples Only

		Reference Method		
		POS	NEG	Total
IsoAmp® HSV Assay	POS	264	35[1]	299
	NEG	8[2]	496	504
	Total	272	531	803

	Value	95% Confidence Interval
Sensitivity	97.1% (264/272)	94.3 – 98.5%
Specificity	93.4% (496/531)	91.0 – 95.2%

[1] 35 samples were tested using bidirectional sequencing analysis. Sequence analysis detected HSV target in 29 [6 HSV-1, 23 HSV-2] of the 35 discordant samples identified as HSV Positive by the IsoAmp® HSV Assay. Sequence analysis did not detect HSV in six (6) of the discordant samples.

[2] Eight (8) samples were tested using bidirectional sequencing analysis. Sequence analysis did not detect HSV target in four (4) of the 8 samples identified as HSV Negative by the IsoAmp® HSV Assay. Sequence analysis did detect HSV in four (4) samples [2 HSV-1, 2 HSV-2]

b. *Oral Samples Only*

		Reference Method		
		POS	NEG	**Total**
IsoAmp® HSV Assay	POS	45	14[1]	59
	NEG	3[2]	97	100
	Total	48	111	159
	Value		**95% Confidence Interval**	
Sensitivity	93.8% (45/48)		83.2 – 97.9%	
Specificity	87.4% (97/111)		79.9 – 92.3%	

II. Retrospective Sample Data

All of the 32 retrospective samples, 15 genital and 17 oral samples were shown positive by both the IsoAmp® HSV Assay and the reference assay.

8.0 Statement of Supporting Data

The results of the analytical and clinical performance studies submitted in this premarket notification are complete and demonstrate that the IsoAmp® HSV Assay is substantially equivalent to the predicate device.

[1] 14 samples were tested using bidirectional sequencing analysis. Sequence analysis detected HSV target in 13 [12 HSV-1, 1 HSV-2] of the 14 discordant samples identified as HSV Positive by the IsoAmp® HSV Assay. Sequence analysis did not detect HSV in one (1) of the discordant samples.

[2] Three (3) samples were tested using bidirectional sequencing analysis. Sequence analysis did not detect HSV target in two (2) of the 3 samples identified as HSV Negative by the IsoAmp® HSV Assay. Sequence analysis did detect HSV in one (1) samples [1 HSV-1]

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

BioHelix Corporation
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Beverly, MA 01915

SEP 27 2011

Re: K111951

Trade/Device Name:	IsoAmp® HSV Assay
Regulation Number:	21 CFR §866.3305
Regulation Name:	Herpes Simplex Virus Nucleic Acid Amplification Assay
Regulatory Class:	Class II
Product Code:	OQO
Dated:	July 6, 2011
Received:	July 8, 2011

Dear Ms. White:

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 class II (Special Controls), 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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 Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 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

Indications for Use

510(k) Number (if known): K111951

Device Name: IsoAmp® HSV Assay

Indications for Use:

The IsoAmp® HSV Assay is an *in vitro* diagnostic test for the direct, qualitative detection of herpes simplex virus (HSV-1 & HSV-2) DNA in male and female genital and oral lesions. The test is intended for use as an aid in diagnosis of HSV infection in symptomatic patients.

***Warning*: The IsoAmp® HSV Assay is not FDA cleared for use with cerebrospinal fluid (CSF). The assay does not provide specific typing information to differentiate HSV-1 and HSV-2. The assay is not intended to be used for prenatal screening.**

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Tamara Feldblyum

Division Sign-Off
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