K100336

MAY 12 2010

510(k) Summary
MultiCode®-RTx Herpes Simplex Virus 1 & 2 Kit

1.0 Submitter

EraGen Biosciences, Inc.
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Contact Person

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Date of Summary Preparation

February 1, 2010

2.0 Device Identification

Product Name:	MultiCode®-RTx Herpes Simplex Virus 1 & 2 Kit
Common Name:	Herpes Simplex Virus 1 and 2 Real-Time PCR Assay
Classification:	Class II
Product Code:	OQO
Regulation Number:	21 CFR 866.3305

3.0 Device to Which Substantial Equivalence is Claimed

Diagnostic Hybrids, Inc.

ELVIS® HSV ID/Typing Test System

510(k) Number: K971662

4.0 Description of Device

The EraGen MultiCode®-RTx Herpes Simplex Virus 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) DNA using vaginal swab specimens.

Patient vaginal swab specimens are collected in Copan Universal Transport Medium, or identical Copan manufactured media formulations (Becton Dickinson Universal Viral Transport Media, Copan branded Universal Transport Medium for LabCorp, and the Quest Viral Culture Media) and transported to the laboratory. An extractable sample processing control (SPC) target is added to the specimen prior to lysis. The SPC controls for specimen lysis, for recovery of extracted nucleic acid, for inhibitory substances and for PCR reagent and instrument integrity. The specimen is lysed and nucleic acid is extracted using the Roche MagNA Pure LC instrument using the Roche MagNA Pure LC Total Nucleic Acid Isolation Kit.

A sample of the extracted nucleic acid is added to the MultiCode®-RTx Herpes Simplex Virus 1 & 2 Kit reagents that contain a primer pair specific to HSV-1 and HSV-2 and a second primer pair specific to the SPC sequence. The two specific primer pairs are labeled with distinct fluorophore labels. PCR amplification is performed and assay fluorescence is monitored using the Roche LightCycler 1.2 real-time PCR instrument. Incorporation of the quencher-labeled nucleotide causes a decrease in assay fluorescence. Following amplification, the reaction is slowly heated and fluorescence is monitored. The strands of the amplification products will separate at a specific melting temperature (T_m) that is determined by an increase in fluorescence as the strands are separated. The instrument fluorescence output is analyzed and test results are determined using the MultiCode®-RTx Herpes Simplex Virus 1 & 2 Kit Analysis Software. A printed results report is generated.

The following reagents, software and instructions for use are supplied with the MultiCode®-RTx Herpes Simplex Virus 1 & 2 Kit:

- HSV-1&2 Reaction Buffer
- HSV-1&2 Primer Mix
- HSV-1 Positive Control
- HSV-2 Positive Control
- Sample Processing Control
- Nuclease Free Water
- Analysis Software

- Certificate of Analysis
- Package Insert

The MultiCode®-RTx Herpes Simplex Virus 1 & 2 Kit reagents are intended to be stored at -15°C to -30°C and are stable until the expiration date indicated on the box.

The following ancillary reagents are required to perform the test but are not supplied:

- Specific lots of the ancillary reagent Clontech TITANIUM® *Taq* DNA Polymerase have been qualified for use with the MultiCode®-RTx HSV 1&2 Kit by EraGen Bioscience.

  NOTE: The MultiCode®-RTx HSV 1&2 Kit product performance requires that only qualified manufacturer lots of Clontech TITANIUM® *Taq* DNA Polymerase be used with the device. Any lots not specifically qualified by EraGen Bioscience for use with the MultiCode®-RTx HSV 1&2 Kit are not validated for use with this assay, and may cause erroneous results.

  To find an up to date list of Qualified Clontech TITANIUM® *Taq* DNA Polymerase go to the EraGen Bioscience website Support page support@eragen.com or call Customer Support at (866) 327-3290.

  Use ancillary reagents only with the instructions for use contained here in this package insert. Discard any instructions for use that may be packaged with these ancillary reagents.

  Any assay problems or failures that are suspected to involve the Clontech TITANIUM® *Taq* DNA Polymerase should be reported to EraGen Biosciences, Inc.

- Copan Universal Transport Medium, or identical Copan manufactured media formulations (Becton Dickinson Universal Viral Transport Media, Copan branded Universal Transport Medium for LabCorp, and the Quest Viral Culture Media) – for use as the Kit Negative Control
- Roche MagNA Pure LC Total Nucleic Acid Isolation Kit

Ancillary reagents are only to be used in accordance with the MultiCode®-RTx Herpes Simplex Virus 1 & 2 Kit package insert.

The following equipment and supplies are required to perform the test, but are not supplied:

- Roche MagNA Pure LC Instrument
- Roche LightCycler version 1.2 instrument with LightCycler software version 3.5
- LightCycler Carousel Centrifuge
- LightCycler Capillaries
- LightCycler Centrifuge Adapters in Cooling Block
- Vortex
- Minicentrifuge
- Appropriate sized pipetters and associated aerosol-barrier tips
- Appropriate sized screw cap tubes and caps

5.0 Indications for Use

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 (HSV1&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 not 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.**

6.0 Intended Use

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 (HSV1&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 not 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.**

7.0 Comparison of the New Device with the Predicate Device

The EraGen Bioscience, Inc. MultiCode®-RTx Herpes Simplex Virus 1 & 2 Kit claims substantial equivalence to the Diagnostics Hybrid, Inc. ELVIS® HSV ID/Typing Test System (K971662). Table 1 identifies the characteristics of EraGen Bioscience, Inc. MultiCode®-RTx Herpes Simplex Virus 1 & 2 Kit (New Device) and the Diagnostics Hybrid, Inc. ELVIS® HSV ID/Typing Test System (Predicate Device).

Table 1. Comparison of New Device with Predicate Device

Device Characteristic	EraGen Biosciences MultiCode®-RTx Herpes Simplex Virus 1 & 2 Kit (New Device)	Diagnostics Hybrid, Inc. ELVIS® HSV ID/Typing Test System (Predicate Device)
Indications for Use	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 (HSV1&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 not 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.**	The ELVIS® HSV ID Typing Test System is a qualitative test indicated for use in isolation and identification of HSV from lesions and body fluids suspected of containing viable HSV-1 and/or HSV-2. Both serotypes have been isolated in various parts of the body, particularly when HSV-associated disease is indicated. Performance of this assay has not been established for use with antiviral therapy or prenatal monitoring.
Identification and Typing of HSV-1 and HSV-2	Yes.	Yes.
Assay Results	Qualitative.	Qualitative.
Assay Type	Real-Time PCR.	Cell Culture using an enzyme linked virus inducible system.
Packaging	The product is supplied in labeled, sterile tubes. The outer container is a labeled box.	The product is supplied in a labeled, sterile tube. The outer container is a labeled box.
Analysis Software Provided	Yes.	No.

Device Characteristic	EraGen Biosciences MultiCode®-RTx Herpes Simplex Virus 1 & 2 Kit (New Device)	Diagnostics Hybrid, Inc. ELVIS® HSV ID/Typing Test System (Predicate Device)
Printed Results Report Provided	Yes.	No.
Kit Reagent Storage Conditions	-15°C to -30°C	2°C to 8°C and 22°C to 28°C

8.0 Test Principle

Following nucleic acid extraction from a patient swab specimen, a fluorophore-labeled PCR primer pair amplifies a segment of the glycoprotein B gene of HSV-1 and HSV-2. The sample processing control (SPC) will also be amplified by a distinct fluorophore-labeled PCR primer pair unless there are sample processing errors, inhibitory substances in the PCR reaction, reagent failure, or instrument malfunction.

The MultiCode®-RTx system is based on an expanded genetic alphabet technology, consisting of 2'-deoxy-5-methyl-isocytidine (iC) and 2'-deoxy-isoguanosine (iG) nucleotide bases also known as isobases. The isobases pair specifically with each other and not with natural nucleotides. In addition isobases are efficiently incorporated during PCR. The isobase pair allows site-specific incorporation of a dabcyl quencher directly adjacent to a fluorophore-labeled primer. During PCR amplification, a quencher-modified iGTP is incorporated by the polymerase opposite an iC and a fluorophore reporter attached to a PCR primer. If target is present and is amplified, assay fluorescence decreases with every cycle as amplification product accumulates. The decrease in assay fluorescence is monitored in real time using the Roche LightCycler 1.2 instrument. Following PCR, the amplification products are thermally denatured and assay fluorescence is monitored. The strands of the amplification products are separated and assay fluorescence increases, thus determining the melting temperature (T_m) profile of the amplicon. The sequences between the PCR primer binding sites of the HSV-1 and HSV-2 amplicons have different base compositions that are distinguished by their different melting temperatures.

9.0 Performance Characteristics

1. Analytical Performance

   a. Precision/Reproducibility:

      The Precision/Reproducibility of the MultiCode®-RTx Herpes Simplex Virus 1 & 2 Kit was evaluated at three U.S. clinical laboratories. A panel was prepared containing six simulated HSV-1 and HSV-2 samples that included High Negative, Low Positive (near the assay limit of detection) and High Positive samples. The

panel, along with external HSV-1 and HSV-2 positive and negative controls, was assayed in triplicate. Kit positive and negative controls were included with each assay run. Panels and controls were tested at each site by 2 operators, 1 time each per day for 5 days (N = 900).

Targets	Site #1				Site #2				Site #3				Total agreement with expected results (%)	95% Confidence Interval
	Agreement with expected results- # correct / #tested	Avg T_m[1]	%CV-T_m	Avg % Deflection[2]	Agreement with expected results- # correct / #tested	Avg Tm[1]	%CV-T_m	Avg % Deflection[2]	Agreement with expected results- # correct / #tested	Avg Tm[1]	%CV-T_m	Avg % Deflection[2]		
HSV-1 Positive Control	10/10	84.3	0.19	85.0	10/10	84.7	0.36	78.3	10/10	84.7	0.22	72.8	30/30 (100%)	88.4%-100%
HSV-2 Positive Control	10/10	87.2	0.21	70.9	10/10	87.7	0.32	70.3	10/10	87.7	0.17	68.8	30/30 (100%)	88.4%-100%
HSV-1/HSV-2 Negative Control[1]	10/10	77.9	0.18	1.5	10/10	78.0	0.28	1.4	10/10	78.0	0.21	1.8	30/30 (100%)	88.4%-100%
PN 1750 HSV-1 Positive External Control	30/30	84.5	0.37	79.2	29/30	84.6	0.27	68.3	30/30	84.7	0.24	67.3	89/90 (98.9%)	93.9% - 100%
PN 1751 HSV-2 Positive External Control	30/30	87.4	0.40	73.0	29/30	87.6	0.28	68.2	30/30	87.7	0.23	69.3	89/90 (98.9%)	93.9% - 100%
PN 1754 HSV-1/HSV-2 Negative External Control[1]	30/30	77.6	0.40	1.6	30/30	77.7	0.43	1.3	30/30	77.8	0.29	1.1	90/90 (100%)	95.9% -100%
HSV-1 High Negative[1]	30/30	77.6	0.39	2.2	30/30	77.7	0.44	2.3	30/30	77.8	0.32	1.4	90/90 (100%)	95.9% -100%
HSV-1 -Low Positive	30/30	84.4	0.37	75.7	29/30	84.5	0.26	64.3	30/30	84.6	0.21	65.1	89/90 (98.9%)	93.9% - 100%
HSV-1 High Positive	30/30	84.5	0.36	94.4	30/30	84.6	0.20	92.8	30/30	84.8	0.21	94.3	90/90 (100%)	95.9% -100%
HSV-2 High Negative[1]	30/30	77.6	0.41	1.2	30/30	77.7	0.28	1.5	30/30	77.7	0.27	1.3	90/90 (100%)	95.9% -100%
HSV-2 Low Positive	30/30	87.3	0.41	71.9	30/30	87.5	0.25	63.5	30/30	87.6	0.19	67.5	90/90 (100%)	95.9% -100%
HSV-2 High Positive	30/30	87.4	0.39	92.9	30/30	87.5	0.19	89.4	30/30	87.7	0.20	91.9	90/90 (100%)	95.9% -100%

[1]: For the HSV-1/HSV-2 Negative Control, the PN1754 HSV-1/HSV-2 Negative Extraction Control as well as the HSV-1 High Negative and HSV-2 High Negative, the T_m value of Sample Processing Control (SPC) was used, since these targets did not generate any detectable HSV-1 or HSV-2 signal.

[2]: % deflection is the individual sample deflection obtained during the melt curve analysis expressed as a percent of the maximum deflection of the melt curve in that assay run. Average % deflection is the average deflection for that panel member across all the 10 runs for the site.

b. Linearity/Assay Reportable Range:

No applicable

c. Traceability, Stability, Expected Values:

Stability studies were performed in-house to determine the shelf life for the MultiCode®-RTx Herpes Simplex Virus 1 & 2 Kit. Product claims are as follows:

- Accelerated Stability: The product is stable for a minimum of 15 months when stored at an accelerated temperature of 4°C.

- Real-Time Stability: The product is stable for a minimum of 6 months when stored the recommended storage temperature of -15°C to -30°C.

Real time stability studies will continue to be performed to support the shelf life of this product.

d. Limit of Detection /Limit of Blank:

A Limit of Detection (LoD) and Limit of Blank (LoB) study was performed at EraGen Biosciences to determine the analytical LoD and LoB performance using quantified ($TCID_{50}$/mL) cultures of HSV-1 and HSV-2 serially diluted in Copan Universal Transport Media. Each viral strain was extracted using the MagNA Pure LC and tested in replicates of 60 per concentration of virus. The LoD was determined to be the lowest concentration of target that was detected in at least 95% of replicates. The LoB was determined to be the highest concentration of target that was detected in ≤ 5% of replicates.

The LoD for HSV-1 was determined to be 2.0×10^3 $TCID_{50}$/mL. At this concentration, 100% of samples were detected with a 95% Confidence Interval of 93.94 – 100%. The LoD for HSV-2 was determined to be 6.4×10^1 $TCID_{50}$/mL. At this concentration, 98.3% of samples were detected with a 95% Confidence Interval of 91.06 – 99.96%.

The LoB for HSV-1 was determined to be 2.5×10^2 $TCID_{50}$/mL. At this concentration, 3.33% of samples were detected with a 95% Confidence Interval of 0.41 – 11.53%. The LoB for HSV-2 was determined to be 4.0 $TCID_{50}$/mL. At this concentration, 0.00% of samples were detected with a 95% Confidence Interval of 0.00 – 5.96%.

LoD for HSV-1

$TCID_{50}$/mL	Pos/Total Calls	Positivity	95% C.I.	
4.00×10^3	59/59*	100.00%	91.06 ± 99.96%	
2.00×10^3	59/59*	100.00%	91.06 ± 99.96%	**LoD**
1.00×10^3	17/60	28.33%	17.45 ± 41.44%	
5.00×10^2	6/59*	10.17%	4.82 ± 22.57%	
2.50×10^2	2/60	3.33%	0.41 ± 11.53%	**LoB**
1.25×10^2	0/60	0.00%	0.00 ± 5.96%	

*One "Invalid" call due to baselines of amp curves by newest V2.0 RC1 software

LoD for HSV-2

$TCID_{50}$/mL	Pos/Total Calls	Positivity	95% C.I.	
1.28×10^2	60/60	100.00%	94.04 ± 100.00%	
6.40×10^1	59/60	98.33%	91.06 ± 99.96%	**LoD**
3.20×10^1	56/60	93.33%	83.80 ± 98.15%	
1.60×10^1	17/57*	29.82%	18.43 ± 43.40%	
8.00	4/60	6.67%	1.85 ± 16.20%	
4.00	0/60	0.00%	0.00 ± 5.96%	**LOB**

*Three "Invalid" calls due to baselines of amp curves by newest V2.0 RC1 software

e. Analytical Specificity and Cross Reactivity:

Analytical Specificity/Cross Reactivity of the MultiCode®-RTx HSV 1&2 Kit was evaluated at EraGen Biosciences. A panel was prepared containing 22 different organisms representing near-neighbors to the HSV-1 and HSV-2 virus and organisms reasonably expected to be present in vaginal swab specimens.

The cross-reactivity panel was tested in a background of Copan Universal Transport Media at the concentration indicated in the table below. Samples were extracted using the Roche MagNA Pure LC and tested in triplicate. No HSV positive results were observed for any of the organisms tested and the DNA SPC was detected in all cases. The organism panel was also spiked into HSV-1 and HSV-2 near the device's Limit of Detection (LoD) and tested.

No interference was observed from any of the tested organisms, and all the results were positive for HSV-1 or HSV-2 as expected.

Organism	Concentration
Candida albicans	2.8 x10^7 CFU/mL
Chlamydia trachomatis	2.5 x10^8 EBs/mL
Escherichia coli	2.0 x10^7 CFU/mL
Mycoplasma hominis	4.5 x10^5 CFU/mL
Neisseria gonorrhoeae	1.8 x10^6 CFU/mL
Staphylococcus aureus	2.4 x10^7 CFU/mL
Staphylococcus saprophyticus	1.2 x10^7 CFU/mL
Streptococcus pyogenes	1.4 x10^7 CFU/mL
Trichomonas vaginalis	1.1 x10^7 CFU/mL
Bacteroides fragilis	3.3 x10^7 CFU/mL
Gardnerella vaginalis	1.4 x10^6 CFU/mL
Mobiluncus mulieris	1.0 x10^7 CFU/mL
Toxoplasma gondii	6.6 x10^5 tachyzoites/mL
Treponema pallidum	1.0 x10^7 CFU/mL
Cytomegalovirus (AD169 strain)	4.2 x10^3 TCID50/mL
Enterovirus (Type 71)	1.4 x10^4 TCID50/mL
Epstein-Barr virus (B95-8 strain)	9.3 x10^7 copies/mL
Varicella Zoster virus	2.4 x10^7 copies/mL
Human Herpes 6 virus (Z29 strain)	1.9 x10^6 TCID50/mL
Human Herpes 7 virus (SB strain)	3.4 x10^6 TCID50/mL
Human Papilloma virus	5 – 8 x10^5 copies/mL
Rubella virus	1.7 x10^4 TCID50/mL

f. Interfering Substances:

An Interfering Substance study was performed at EraGen Biosciences to evaluate the effects of potential interfering substances on the MultiCode®-RTx HSV 1&2 Kit. A panel was prepared containing 6 substances that could reasonably be expected to be present in vaginal swab specimens. The substance panel was tested near the device's Limit of Detection (LoD) for HSV-1 and HSV-2. No interference was observed in the presence of exogenous and endogenous substances in an extractable sample.

Substance	Concentration
Whole Blood (with EDTA)	10%
Whole Blood (with EDTA)	1%
Female Urine	10%
Female Urine	1%
Protein (Albumin)	10 mg/ml

Substance	Concentration
Protein (Albumin)	1 mg/ml
Protein (Casein)	10 mg/ml
Protein (Casein)	1 mg/ml
K-Y Brand Jelly	5%
K-Y Brand Jelly	0.5%
Acyclovir (Acycloguanosine)	2.5 mg/ml
Acyclovir (Acycloguanosine)	0.25 mg/ml

g. Competitive Inhibition:

Competitive Inhibition of the MultiCode®-RTx HSV 1&2 Kit was evaluated internally using simulated samples with varying concentrations of HSV-1 virus (1X LoD to 1000X LoD) and HSV-2 virus (1X LoD to 1000X LoD). Competitive inhibition was observed. The highest concentration of co-infecting target that can be present while maintaining 95% detection of the 3X LoD target for HSV-1 was 1X LoD for HSV-2. The highest concentration of co-infecting target that can be present while maintaining 95% detection of the 3X LoD target for HSV-2 was 1X LoD for HSV-1.

Competitive Inhibition was also evaluated internally using simulated samples with equal concentrations of HSV-1 virus and HSV-2 virus (5X LoD to 500X LoD). Competitive inhibition was not observed at any of the concentrations tested when the concentrations of HSV-1 and HSV-2 were equal.

h. Carry-over/Contamination:

Carry-over/Contamination studies were done only with HSV-1 target, since both HSV-1 and HSV-2 share a single set of primers. The MultiCode®-RTx HSV 1&2 Kit was evaluated internally using simulated samples at the LoB and High Positive HSV-1 (1700X LoD) samples. Ten sets of samples in a sequence pattern of High Positive-LoB-LoB were aliquoted into a 32-well sample plate and extracted using the Roche MagNA Pure LC instrument. The high positive sample was positive for HSV-1 in all cases and all LoB samples were negative for HSV-1 indicating that there was no carry-over/cross-contamination of HSV-1 in the LoB samples.

i. Assay Cut-Off:

Not Applicable

2. Clinical Performance:

Performance characteristics of the MultiCode®-RTx HSV 1&2 Kit were established during a prospective study performed at three U.S. clinical laboratories during 2008-2009. Vaginal lesion swab specimens were sent to the clinical laboratory for routine Herpes Simplex Virus testing.

The reference method was a cell culture based ELVIS® Herpes Simplex Virus identification and typing test. A total of 1041 vaginal swab specimens were tested by the MultiCode®-RTx HSV 1&2 Kit and by the reference method.

Results from Prospective Study:

Herpes Simplex Virus Type 1 Comparison Results				
		Reference Method		
		Positive	Negative	Total
MultiCode®-RTx HSV 1&2 Kit	Positive	97	16[a]	113
	Negative	8[b]	920	928
	Total	105	936	1041
		Value	**95% Confidence Interval**	
Sensitivity		92.4%	85.7 – 96.1%	
Specificity		98.3%	97.2 – 98.9%	

[a] Sequence analysis detected HSV-1 in 12 of the 16 discordant samples identified as HSV-1 by MultiCode®-RTx. Sequence analysis did not detect HSV-1 in 4 of the discordant samples.

[b] Sequence analysis detected HSV-1 in 1 of the 8 discordant samples identified as HSV-1 negative by MultiCode®-RTx. Sequence analysis did not detect HSV-1 in 7 of the discordant samples. Of these 7 discordant samples: 4 of the samples were identified as HSV-2 by both MultiCode®-RTx and sequencing, 2 of the samples were negative by MultiCode®-RTx and not detected by sequencing, and 1 sample was negative by MultiCode®-RTx and HSV-2 positive by sequencing.

Herpes Simplex Virus Type 2 Comparison Results				
		Reference Method		
		Positive	Negative	Total
MultiCode®-RTx HSV 1&2 Kit	Positive	198	53[a]	251
	Negative	10[b]	780	790
	Total	208	833	1041
		Value	**95% Confidence Interval**	
Sensitivity		95.2%	91.4 – 97.4%	
Specificity		93.6%	91.8 – 95.1%	

[a] Sequence analysis detected HSV-2 in 43 of the 53 discordant samples identified as HSV-2 by MultiCode®-RTx. Sequence analysis did not detect HSV-2 in 10 of the discordant samples.

[b] Sequence analysis detected HSV-2 in 2 of the 10 discordant samples identified as HSV-2 negative by MultiCode®-RTx. Sequence analysis did not detect HSV-2 in 8 of the discordant samples. These 8 samples were identified as HSV-1 by both MultiCode®-RTx and sequencing.

A total of 69 specimens were reference method negative and MultiCode®-RTx HSV 1&2 Kit positive for HSV-1 or HSV-2. DNA sequencing analysis agreed in 55 of these 69 specimens with the MultiCode®-RTx HSV 1&2 Kit.

10.0 Statement of Supporting Data

Real time stability studies will be ongoing to support the shelf life of this product. Supporting data for all studies performed is retained on file at EraGen Biosciences, Inc.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center-WO66-G609
Silver Spring, MD 20993-0002

MAY 12 2010

Mr. Randal Vader
Vice President
Quality, Regulatory and Clinical Affairs
Eragen Biosciences, Inc.
918 Deming Way Suite 201
Madison, Wisconsin 53717

Re: K100336

Trade/Device Name:	MultiCode®-RTx Herpes Simplex Virus 1 & 2 Kit
Regulation Number:	21CFR §866.3305
Regulatory Name:	Herpes Simplex Virus Nucleic Acid Amplification Assay
Regulatory Class:	Class II
Product Code:	OQO
Dated:	March 6, 2010
Received:	March 8, 2010

Dear Mr. Vader:

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 the Code of Federal Regulations, Title 21, Parts 800 to 898. 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); good manufacturing practice requirements

as set forth in the quality systems (QS) regulation (21 CFR Part 820); and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050. 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 Part 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): K100336

Device Name: MultiCode®-RTx Herpes Simplex Virus 1 & 2 Kit

Indications for Use:

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 (HSV1&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 not 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.**

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 Device Evaluation (ODE)

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K100336