October 29, 2018

ELITechGroup
Walt Mahoney
Regulatory Affairs Manager
21720 23rd Drive SE Suite 150
Bothell, Washington 98021

Re: K180559
Trade/Device Name: HSV 1 & 2 ELITe MGB Kit; ELITe InGenius
Regulation Number: 21 CFR 866.3309
Regulation Name: Herpes virus nucleic acid-based cutaneous and mucocutaneous lesion panel
Regulatory Class: Class II
Product Code: PGI, OOI
Dated: January 17, 2018
Received: March 1, 2018

Dear Walt Mahoney:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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 Part 801 and Part 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Steven R. Gitterman -S for

Uwe Scherf, Ph.D.
Director
Division of Microbiology Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K180559

Device Name
HSV 1&2 ELITe MGB Assay

Indications for Use *(Describe)*

HSV 1&2 ELITe MGB Assay
The HSV 1&2 ELITe MGB® Assay is a real-time polymerase chain reaction (PCR) based qualitative in vitro diagnostic test for the direct detection and differentiation of Herpes Simplex Virus 1 and 2 (HSV-1 and HSV-2) DNA in cutaneous or mucocutaneous lesion swab specimens from patients with signs and symptoms of HSV-1 or HSV-2 infection. This test is an aid in the differential diagnosis of HSV-1 and HSV-2 infections.
The HSV 1&2 ELITe MGB Assay is not FDA cleared for use with cerebrospinal fluid (CSF) specimens. The assay is not intended to be used for prenatal screening or for screening blood or blood products.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary

ELITe MGB HSV 1&2 Assay on the ELITe InGenius system

1.	**Date:**	September 25th, 2018
2.	**Submitter:**	ELITechGroup Inc. Molecular Diagnostics 21720 23rd Drive SE, Suite 150 Bothell, WA 98021
3.	**Contact Person:**	Walt Mahoney 21720 23rd Dr. SE, Suite 150 Bothell, WA 98021 Phone: 425-482-5173 Fax: 425-482-5550 Email: w.mahoney@elitechgroup.com
4.	**Device Description:**	K180559 HSV 1&2 ELITe MBG Assay Class II PGI 21CFR 866.3309
5.	**Predicate Devices:**	K151906 LUMINEX Corporation ARIES® HSV 1&2 Assay

6. **Intended Use**

HSV 1&2 ELITe MGB Assay	The HSV 1&2 ELITe MGB® Assay is a real-time polymerase chain reaction (PCR) based qualitative in vitro diagnostic test for the direct detection and differentiation of Herpes Simplex Virus 1 and 2 (HSV-1 and HSV-2) DNA in cutaneous or mucocutaneous lesion swab specimens from patients with signs and symptoms of HSV-1 or HSV-2 infection. This test is an aid in the differential diagnosis of HSV-1 and HSV-2 infections. The HSV 1&2 ELITe MGB Assay is not FDA cleared for use with cerebrospinal fluid (CSF) specimens. The assay is not intended to be used for prenatal screening or for screening blood or blood products.

Special instrument requirements: for use on the ELITe InGenius system

7. **Device Descriptions**

HSV 1&2 ELITe MGB Assay

The HSV 1&2 ELITe MGB Assay is a qualitative in vitro diagnostic Real-Time PCR Assay for the direct detection of Herpes Simplex Virus (HSV) DNA (glycoprotein D gene for HSV-1 and glycoprotein G gene for HSV-2) in symptomatic male and female patients using DNA purified from swab specimens collected from individuals with cutaneous or mucocutaneous herpetic lesions.

The HSV 1&2 ELITe MGB Assay system is comprised of three major processes: (1) automated preparation of unprocessed sample to extract nucleic acids from primary swab specimens using the ELITe InGenius SP 200 Extraction Cartridge, (2) PCR amplification of target DNA sequences using HSV-1 and HSV-2 specific primers, and (3) real-time detection of fluorescent-labeled HSV-1 and HSV-2 specific oligonucleotide detection probes.

An Internal Control (IC), containing unrelated randomized DNA sequence, is added to all samples prior to extraction and monitors the integrity of the reagents, equipment function, and the presence of inhibitors in the samples. A positive signal in the Internal Control channel in the absence of HSV DNA indicates that the PCR has not been inhibited.

The amplification reagents, Positive Control and Internal Control are packaged as part of the HSV 1&2 ELITe MGB Assay.

8. **Substantial Equivalence Information**

Device Name: HSV 1&2 ELITe MGB Assay
Predicate Device Name: Aries HSV 1&2 Assay, 510k number: K151906

Comparison with predicate

Similarities

Item	New Device HSV 1&2 ELITe MGB Assay	Predicate Device Aries HSV 1&2 Assay, K151906
Intended Use/Indications for Use	The HSV 1&2 ELITe MGB® Assay is a real-time polymerase chain reaction (PCR) based qualitative in vitro diagnostic test for the direct detection and differentiation of Herpes Simplex Virus 1 and 2 (HSV-1 and HSV-2) DNA in cutaneous or mucocutaneous lesion swab specimens from patients with signs and symptoms of HSV-1 or HSV-2 infection. This test is an aid in the differential diagnosis of HSV-1 and HSV-2 infections. The HSV 1&2 ELITe MGB Assay is not FDA Cleared for use with cerebrospinal fluid (CSF) specimens. The assay is not intended to be used for prenatal screening or for screening blood or blood products.	The ARIES® HSV 1&2 Assay is a real-time polymerase chain reaction (PCR) based qualitative in vitro diagnostic test for the direct detection and differentiation of Herpes Simplex Virus 1 and 2 (HSV 1 and HSV 2) DNA in cutaneous or mucocutaneous lesion specimens from symptomatic patients. The test is indicated for use as an aid in diagnosis of HSV infection in symptomatic patients. The ARIES® HSV 1&2 Assay is indicated for use on the ARIES® System. WARNING: The ARIES® HSV 1&2 Assay is not FDA cleared for use with cerebrospinal fluid (CSF). The assay is not intended to be used for prenatal screening.
Specimen types	Male and female cutaneous and mucocutaneous lesion swab specimens	Same
Major Technology	Qualitative real-time PCR	Same
Sample extraction method	Automated sample extraction	Same
Assay results	Qualitative detection and differentiation of HSV-1 and HSV-2 DNA	Same

Differences

Parameter	New Device HSV 1&2 ELITe MGB Assay	Predicate Device Aries HSV 1&2 Assay, K151906
Sample extraction & Amplification Instrumentation	ELITe InGenius system	ARIES system
Analyte measures	DNA sequences from HSV-1 glycoprotein D gene and HSV-2 glycoprotein G gene.	DNA sequences from Herpes Simplex Virus type 1 (HSV-1) and Herpes Simplex Virus type 2 (HSV-2)
Detection Method	Multiplex assay with paired reporter and quencher fluorescence labeled probes and different reporter dyes for each target. Measures increase in assay fluorescence with each PCR cycle.	Pairs fluorescent-labeled primers with quencher labeled nucleotides. Measures decrease in assay fluorescence with each PCR cycle.

9. **Instrumentation/Software:**

The HSV 1&2 ELITe MGB Assay is used on the ELITe InGenius system. The ELITe InGenius system is a bench top instrument integrating all required hardware, reagent and software components to perform nucleic acid sample preparation and real-time PCR operations.
The ELITe InGenius system can process from 1 to 12 samples in 12 parallel tracks, and samples may be loaded in primary tubes or in secondary tubes provided. The system utilizes a universal, cassette-based process for sample extraction, and allows for multiple and independent PCRs to be performed from a single nucleic acid eluate.
The system can operate in three different modes: nucleic acid extraction only, PCR amplification only, or nucleic acid extraction with PCR amplification.

10 **Performance Characteristics – Analytical Performance**

a. Limit of Detection

The analytical sensitivity of the HSV 1&2 ELITe MGB Assay was determined using 4 HSV strains (two for each target). Quantitated viral strains were obtained and diluted with HSV negative pooled human cheek matrix in Universal Transport Medium (UTM) to values spanning the range of approximately .05 to 1000 $TCID_{50}$/mL (depending on the strain). All dilutions were tested, and the limit of detection (LoD) was determined using Probit (Logit) Data Analysis software (Analyse-it for Microsoft Excel v4.80.2, Logistic Function model). LoD for each strain represents the lowest viral titer in $TCID_{50}$/mL at which a positive result will be obtained with at least 95% confidence. LoD for each strain was then verified by testing at least 20 replicates. Results indicate that, depending on the strain, the HSV 1&2 ELITe MGB Assay will produce a positive result with 95% confidence for a swab eluate containing 59 (HSV-1; HSV-1 MacIntyre Strain) and/or 5.4 (HSV-2; HSV-2 MS Strain) $TCID_{50}$/mL.

Limit of Detection Results

Organism	Isolate/Strain	Cell Line	Qualitative results #detected/Total	Mean C_T ±SD from detected replicates	1×LoD $TCID_{50}$/mL
HSV-1	MacIntyre strain	Vero	20/20	37.91 ± 0.69	59.0 $TCID_{50}$/mL
HSV-1	Isolate #15 (Zeptometrix)	Vero	20/20	39.94 ± 0.95	1.5 $TCID_{50}$/mL
HSV-2	MS strain	Vero	20/20	37.90 ± 0.92	5.4 $TCID_{50}$/mL
HSV-2	Isolate #2 (Zeptometrix)	Vero	20/20	38.67 ± 1.03	0.3 $TCID_{50}$/mL

A swab elution efficiency study was also performed by using the same HSV negative pooled human cheek swab matrix and the HSV-1 MacIntyre strain used to verify the LoB. This study showed 100% elution efficiency from the Copan regular flocked swab compared with the same volume of material directly spiked into UTM. Therefore, LoD values in $TCID_{50}$/mL units will be directly proportional (with a constant = 1) to the LoD in $TCID_{50}$/swab units, depending only on the volume of the media in the collection device.

b. Assay Cut Off

The assay cut-off analysis was performed on a separate set of 141 clinical samples collected from 3 clinical sites. Each clinical sample was evaluated using HSV 1&2 ELITe MGB Assay in conjunction with the ELITe InGenius instrument and a composite reference method (FDA-cleared real-time PCR assay combined with PCR amplification and bi-directional sequencing). Both targets in clinical samples were detected up to cycle 45. Therefore C_T of 45 was established as a diagnostic assay cut-off for both HSV-1 and HSV-2 targets.

c. Analytical Reactivity (Inclusivity)

Performance of the HSV 1&2 ELITe MGB Assay was tested on 44 well characterized HSV-1 and HSV-2 isolates, which were obtained through commercial means. All strains were tested with the HSV 1&2 ELITE MGB Assay as spiked samples in UTM that had been prepared at 3×LOD level (177 $TCID_{50}$/mL for HSV-1 and 16.2 $TCID_{50}$/mL for HSV-2). For HSV-1 and HSV-2 viral isolates not detected (negative) at 3×LoD concentrations, 2× incremental concentrations were tested, and the lowest detectable level was determined, and the final test concentration is reported. All of the HSV-1 and HSV-2 tested isolates were detected by the HSV 1&2 ELITe MGB Assay at concentrations of 16.2 – 354 $TCID_{50}$/mL

Summary of Inclusivity Results

#	Isolate	Estimated 1×LoD ($TCID_{50}$/mL)	×LoD Tested	Final Test Conc. ($TCID_{50}$/mL)	Positivity
1	HSV-1 MacIntyre Strain	59	3×	177	3/3
2	HSV-1 Isolate #1	59	3×	177	3/3
3	HSV-1 Isolate #2	59	3×	177	3/3
4	HSV-1 Isolate #3	59	3×	177	3/3
5	HSV-1 Isolate #4	59	3×	177	3/3
6	HSV-1 Isolate #5	59	3×	177	3/3
7	HSV-1 Isolate #6	59	3×	177	0/3
		59	6×	354	3/3
8	HSV-1 Isolate #7	59	3×	177	3/3
9	HSV-1 Isolate #8	59	3×	177	3/3
10	HSV-1 Isolate #9	59	3×	177	3/3
11	HSV-1 Isolate #10	59	3×	177	3/3
12	HSV-1 Isolate #11	59	3×	177	3/3
13	HSV-1 Isolate #12	59	3×	177	3/3
14	HSV-1 Isolate #13	59	3×	177	3/3
15	HSV-1 Isolate #14	59	3×	177	3/3
16	HSV-1 Isolate #15	59	3×	177	3/3
17	HSV-1 Isolate #16	59	3×	177	3/3
18	HSV-1 Isolate #17	59	3×	177	3/3
19	HSV-1 Isolate #18	59	3×	177	3/3
20	HSV-1 Isolate #19	59	3×	177	3/3
21	HSV-1 Isolate #20	59	3×	177	0/3
		59	6×	354	3/3
22	HSV-1 Isolate #21	59	3×	177	3/3
23	HSV-2 MS Strain	5.4	3×	16.2	3/3
24	HSV-2 Isolate #1	5.4	3×	16.2	3/3
25	HSV-2 Isolate #2	5.4	3×	16.2	3/3
26	HSV-2 Isolate #3	5.4	3×	16.2	3/3

27	HSV-2 Isolate #4	5.4	3×	16.2	3/3
28	HSV-2 Isolate #5	5.4	3×	16.2	3/3
29	HSV-2 Isolate #6	5.4	3×	16.2	3/3
30	HSV-2 Isolate #7	5.4	3×	16.2	3/3
31	HSV-2 Isolate #8	5.4	3×	16.2	2/3
		5.4	3×	16.2	3/3
32	HSV-2 Isolate #9	5.4	3×	16.2	3/3
33	HSV-2 Isolate #10	5.4	3×	16.2	3/3
34	HSV-2 Isolate #11	5.4	3×	16.2	2/3
		5.4	6×	32.4	3/3
35	HSV-2 Isolate #12	5.4	3×	16.2	1/3
		5.4	6×	32.4	3/3
36	HSV-2 Isolate #13	5.4	3×	16.2	0/3
		5.4	6×	32.4	2/3
		5.4	12×	64.8	2/3
		5.4	24×	129.6	3/3
37	HSV-2 Isolate #14	5.4	3×	16.2	1/3
		5.4	6×	32.4	3/3
38	HSV-2 Isolate #15	5.4	3×	16.2	0/3
		5.4	6×	32.4	3/3
39	HSV-2 Isolate #16	5.4	3×	16.2	1/3
		5.4	6×	32.4	3/3
40	HSV-2 Isolate #17	5.4	3×	16.2	1/3
		5.4	6×	32.4	1/3
		5.4	12x	64.8	3/3
41	HSV-2 Isolate #18	5.4	3×	16.2	3/3
42	HSV-2 Isolate #19	5.4	3×	16.2	2/3
		5.4	6×	32.4	1/3
		5.4	12×	64.8	3/3
43	HSV-2 Isolate #20	5.4	3×	16.2	0/3
		5.4	6×	32.4	1/3
		5.4	12×	64.8	3/3
44	HSV-2 Isolate #21	5.4	3×	16.2	3/3

d. Analytical Specificity (Cross-Reactivity)

To determine if there are any organisms that could be potential cross-reactive with the HSV 1&2 ELITE MGB Assay the NCBI BLAST in silico (computer) analysis of the HSV-1 and HSV-2 amplicons was performed. Found sequence homology in both the primer and probe regions was not sufficient for HSV1&2 ELITe MGB Assay to potentially cross-react with the non-HSV organisms.

Potential cross-reactivity of the HSV 1&2 ELITe MGB Assay was then evaluated by testing varied species of organisms that are closely related to HSV or cause similar clinical symptoms or may be present in the anogenital and oral cutaneous and mucocutaneous sites tested by this device. 49 potential cross reactants were evaluated. For each organism, the sample to be tested was prepared from quantified stock diluted to the required concentration using UTM.

The potential cross reactants were tested, the concentrations were evaluated and the results are presented in the following table:

No.	Potential Cross-Reactants	Tested Concentration	Qualitative Result (#Detected/#Total)

			HSV-1	HSV-2
1	*Acinetobacter calcoaceticus*	1×10^6 CFU/mL	0/3	0/3
2	*Acinetobacter lwoffi*	1×10^6 CFU/mL	0/3	0/3
3	Adenovirus type 2	1×10^5 $TCID_{50}$/mL	0/3	0/3
4	*Bacteroides fragilis*	1×10^6 CFU/mL	0/3	0/3
5	*Candida albicans*	1×10^6 CFU/mL	0/3	0/3
6	*Candida glabrata*	1×10^6 CFU/mL	0/3	0/3
7	*Candida guilliermondii*	1×10^6 CFU/mL	0/3	0/3
8	*Candida krusei*	1×10^6 CFU/mL	0/3	0/3
9	*Candida lustaniae*	1×10^6 CFU/mL	0/3	0/3
10	*Candida parapsilosis*	1×10^6 CFU/mL	0/3	0/3
11	*Candida tropicalis*	1×10^6 CFU/mL	0/3	0/3
12	*Chlamydia trachomatis*	1×10^6 CFU/mL	0/3	0/3
13	Cytomegalovirus	1×10^5 $TCID_{50}$/mL	0/3	0/3
14	*Enterobacter cloacae*	1×10^6 CFU/mL	0/3	0/3
15	Enterovirus	1×10^5 $TCID_{50}$/mL	0/3	0/3
16	Epstein-Barr Virus	1×10^5 $TCID_{50}$/mL	0/3	0/3
17	*Escherichia coli*	1×10^6 CFU/mL	0/3	0/3
18	*Fusobacterium nucleatum*	1×10^6 CFU/mL	0/3	0/3
19	*Gardnerella vaginalis*	1×10^6 CFU/mL	0/3	0/3
20	*Haemophilus ducreyi*	1×10^6 CFU/mL	0/3	0/3
21	Human Genomic DNA	500 ng/swab	0/3	0/3
22	Human Herpes Virus 6	1×10^5 $TCID_{50}$/mL	0/3	0/3
23	Human Herpes Virus 7	1×10^5 $TCID_{50}$/mL	0/3	0/3
24	Human papilloma virus 16	1×10^5 $TCID_{50}$/mL	0/3	0/3
25	Human papilloma virus 18	1×10^5 $TCID_{50}$/mL	0/3	0/3
26	Herpes Simplex Virus 1 (HSV-1), isolate 20, ZMC	1×10^5 $TCID_{50}$/mL	3/3	0/3
27	Herpes Simplex Virus 2 (HSV-2), isolate 20. ZMC	1×10^5 $TCID_{50}$/mL	0/3	3/3
28	*Klebsiella pneumoniae*	1×10^6 CFU/mL	0/3	0/3
29	*Lactobacillus acidophilus*	1×10^6 CFU/mL	0/3	0/3
30	*Mobiluncus curtsii*	1×10^6 CFU/mL	0/3	0/3
31	*Mobiluncus mulieris*	1×10^6 CFU/mL	0/3	0/3
32	*Moraxella catarrhalis*	1×10^6 CFU/mL	0/3	0/3
33	*Mycoplasma hominis*	1×10^6 CFU/mL	0/3	0/3
34	*Neisseria gonorrhea*	1×10^6 CFU/mL	0/3	0/3
35	*Neisseria meningitides*	1×10^6 CFU/mL	0/3	0/3
36	*Prevotella melaninogenica*	1×10^6 CFU/mL	0/3	0/3
37	Rubella Virus	1×10^5 $TCID_{50}$/mL	0/3	0/3
38	*Staphylococcus aureus (*MSSA)	1×10^6 CFU/mL	0/3	0/3
39	*Staphylococcus epidermidis* (MRSE)	1×10^6 CFU/mL	0/3	0/3
44	*Staphylococcus saprophyticus*	1×10^6 CFU/mL	0/3	0/3
41	*Streptococcus mitis*	1×10^6 CFU/mL	0/3	0/3
42	*Streptococcus mutans*	1×10^6 CFU/mL	0/3	0/3
43	*Streptococcus pneumoniae*	1×10^6 CFU/mL	0/3	0/3
44	*Streptococcus pyogenes*	1×10^6 CFU/mL	0/3	0/3
45	*Streptococcus salivarius*	1×10^6 CFU/mL	0/3	0/3
46	*Toxoplasma gondii*	1×10^6 CFU/mL	0/3	0/3
47	*Trichomonas vaginalis*	1×10^6 CFU/mL	0/3	0/3
48	Varicella-Zoster Virus (VZV)	1×10^5 $TCID_{50}$/mL	0/3	0/3

49	*Chlamydophila pneumoniae*	1×10^6 CFU/mL	0/3	0/3

e. Analytical Specificity (Microbial Interference)

The microbial interference was evaluated in the presence of either HSV-1 or HSV-2 spiked at 3×LoD in UTM and the 49 organisms indicated in the table above. Each microorganism was tested either at 1×10^6 CFU/mL or higher for bacterial isolates, or at 1×10^5 $TCID_{50}$/mL or higher for viruses. None of the non-target organisms that are reasonably expected to be found in cutaneous and mucocutaneous swab samples interfered with the detection of HSV-1 or HSV-2 species. The only exception is that amplification of HSV-1 is completely inhibited in the presence of HSV-2 in titers of 1×10^3 or higher. This observed HSV-2 interference is reported as a limitation in the device package insert.

f. Competitive Interference of HSV-1 and HSV-2

Competitive interference was studied to evaluate the effects of possible clinically relevant co-infection with both HSV-1 and HSV-2 using HSV 1&2 ELITe MGB Assay.

The study assessed whether a high concentration of one virus in the sample could potentially affect the HSV 1&2 ELITe MGB Assay performance for the other target present at low levels. A low positive sample was contrived at approximately 3×LoD for each target (HSV-1 MacIntyre strain and HSV-2 MS strain), and a baseline Ct was determined for each sample. Each potential concomitant infecting virus was spiked into the low level sample and assayed in triplicate.

Competitive interference of HSV-1 with HSV-2 was observed at 1×10^3, 1×10^4, 1×10^5 $TCID_{50}$/mLHSV-2 level. This observed interference information is included as a limitation in the device package insert.

No competitive interference of HSV-2 with HSV-1 at any level was observed. The results of the testing are shown in the table below.

Competitive Interference of HSV-1 and HSV-2 targets at unequal concentrations

Baseline (Low Level)		Competitive Interferent (High Concentration)		Qualitative Results (#Detected/#Total)	
Strain	Concentration ($TCID_{50}$/mL)	Strain	Concentration ($TCID_{50}$/mL)	HSV-1	HSV-2
HSV-1 MacIntyre	177	HSV-2 MS	100000	0/3	3/3
HSV-1 MacIntyre	177	HSV-2 MS	10000	1/3	3/3
HSV-1 MacIntyre	177	HSV-2 MS	1000	1/3	3/3
HSV-1 MacIntyre	177	HSV-2 MS	100	3/3	3/3
HSV-1 MacIntyre	177	HSV-2 MS	0	3/3	0/3
HSV-2 MS	16.2	HSV-1 MacIntyre	100000	3/3	3/3
HSV-2 MS	16.2	HSV-1 MacIntyre	10000	3/3	3/3
HSV-2 MS	16.2	HSV-1 MacIntyre	1000	3/3	3/3
HSV-2 MS	16.2	HSV-1 MacIntyre	100	3/3	3/3
HSV-2 MS	16.2	HSV-1 MacIntyre	0	0/3	3/3

Additionally, in a separate study both strains were tested at similar or equal concentrations of 3×LoD, 1×10^3 and 1×10^5, and no competitive interference was observed.

Competitive Interference of HSV-1 & HSV-2 targets at equal concentrations

HSV-1 Concentration	HSV-2 Concentration	Qualitative Results (#Detected/#Total)	Quantitative Results (%CV)

Strain	$TCID_{50}$/mL	Strain	$TCID_{50}$/mL	HSV-1	HSV-2	HSV-1	HSV-2
HSV-1 MacIntyre	1×10^5	HSV-2 MS	1×10^5	5/5	5/5	3.02 %	1.64 %
HSV-1 MacIntyre	1×10^3	HSV-2 MS	1×10^3	5/5	5/5	1.09 %	2.95 %
HSV-1 MacIntyre	177 (3×LoD)	HSV-2 MS	16.2 (3×LoD)	5/5	5/5	1.74 %	1.88 %

g. Interfering Substances

The performance of the HSV 1&2 ELITe MGB Assay was evaluated with potentially interfering substances that could be encountered in lesion swab specimens obtained from cutaneous and mucocutaneous locations. A total of 33 substances were individually spiked into negative UTM matrix containing one of each HSV-1 and HSV-2 isolates at 3X LoD level and tested in triplicate with the HSV 1&2 ELITe MGB Assay. There were no invalid result calls. No interference was observed (see table below).

Potential Interferent	Interferent Concentration	#Detected/#Total		
		HSV-1	HSV-2	IC
Whole blood with EDTA	5% v/v	0/3	0/3	3/3
Buffy coat	5% v/v	0/3	0/3	3/3
Acyclovir	2.5 mg/mL	0/3	0/3	3/3
Albumin	5 mg/mL	0/3	0/3	3/3
Casein	7 mg/mL	0/3	0/3	3/3
Female urine	10% v/v	0/3	0/3	3/3
Male urine	10% v/v	0/3	0/3	3/3
K-Y Brand jelly	5% w/v	0/3	0/3	3/3
Douche	10% v/v	0/3	0/3	3/3
Spermicide	5% w/v	0/3	0/3	3/3
Yeast·Gard	1% w/v	0/3	0/3	3/3
Monistat 1	5% w/v	0/3	0/3	3/3
Monistat 3	5% w/v	0/3	0/3	3/3
Vagisil Cream	1% w/v	0/3	0/3	3/3
Tioconazole 1	5% w/v	0/3	0/3	3/3
Rite Aid Feminine Wash, Sensitive Skin	10% v/v	0/3	0/3	3/3
Clotrimazole-7 vaginal cream	1% w/v	0/3	0/3	3/3
Oral Analgesic Gel	5% w/v	0/3	0/3	3/3
Listerine antiseptic mouthwash	10% v/v	0/3	0/3	3/3
Abreva	10% v/v	0/3	0/3	3/3
Carmex lip balm	1% w/v	0/3	0/3	3/3
Releev cold sore treatment	1% v/v	0/3	0/3	3/3
Lip Clear lysine	1% w/v	0/3	0/3	3/3
Toothpaste	5% w/v	0/3	0/3	3/3
Acetaminophen	5 mg/mL	0/3	0/3	3/3
Wal-Finate	5 mg/mL	0/3	0/3	3/3
Cold-Eeze	7% w/v	0/3	0/3	3/3
Non-GMO Corn Starch	1.25 mg/mL	0/3	0/3	3/3
Zinc Oxide Ointment	7% w/v	0/3	0/3	3/3
Cough DM	10mg/mL	0/3	0/3	3/3
Lanacane Max Strength anti-itch cream	7% w/v	0/3	0/3	3/3
Seminal fluid	7% v/v	0/3	0/3	3/3
Foscarnet sodium	5% v/v	0/3	0/3	3/3

h. Carry-Over Contamination

The sample-to-sample carry-over from positive samples into the negative samples for the HSV 1&2 ELITe MGB Assay was studied by performing 5 integrated checkerboard runs (high positive for HSV-1 at 2.5×10^7 $TCID_{50}$/mL concentration and negative samples (UTM) interspersed), which were compared to the overall contamination level ("background noise") of 2 negative sample runs. One operator ran 7 runs (5 checkerboard runs and 2 complete negative runs). The High positive sample concentration in this study were high enough to exceed 95% or more of the concentration levels obtained from specimens of infected patients in the intended use population. No carry-over and cross contamination was observed. Overall percent agreement was 100% for positive and negative samples.

Carry-Over and Cross-Contamination Results

Run description	Positive Samples		Negative Samples	
	# Neg	% Neg.	# Pos.	% Pos.
Run #1, BLANK	0 / 0	NA	0 / 10	0 %
Run #2, Checkerboard	0 / 5	0 %	0 / 6	0 %
Run #3, Checkerboard	0 / 6	0 %	0 / 6	0 %
Run #4, BLANK	0 / 0	NA	0 / 10	0 %
Run #5, Checkerboard	0 / 6	0 %	0 / 6	0 %
Run #6, Checkerboard	0 / 6	0 %	0 / 6	0 %
Run #7, Checkerboard	0 / 6	0 %	0 / 6	0 %
All runs	0 / 29	0 %	0 / 50	0 %

i. Sample Stability

This study assessed both sample stability and sample freeze-thaw stability. The samples for the stability evaluation were prepared by spiking both the HSV-1 and HSV-2 vendor quantitated viral stocks (HSV-1 MacIntyre strain and HSV-2 MS strain) in UTM, M4, M4RT, M5 and M6 media.

Each stability sample set consisted of:

- 5 replicates spiked at 3×LoD,
- 5 replicates spiked at 1×10^3 $TCID_{50}$/mL, and
- 5 replicates spiked at 1×10^5 $TCID_{50}$/mL (15 replicates total for each sample set).

The stability of each sample set was assessed by sample incubation at +4°C for 1 week. All HSV-1 and HSV-2 samples were confirmed to be stable in UTM, M4, M4RT, M5 and M6 media for 1 week at +4°C.

The storage conditions were also validated by re-testing previously analyzed clinical samples that were stored in a -80°C freezer (≤ -70°C) for minimum of 4 months. Sample concentrations covered HSV clinical range. Ten HSV-1 or HSV-2 positive samples were tested for each media (except M6 for which only 7 HSV-positive samples were available). Positivity of all samples was confirmed after 4 month storage in a -80°C freezer (≤ -70°C).

A freeze thaw study was performed using 5 sample sets prepared as in the above using UTM, M4, M4RT, M5 and M6 media. All samples were subjected to 3 freeze-thaw cycles. All the samples were tested with the HSV 1&2 ELITe MGB Assay on the ELITe InGenius. The data obtained show that HSV-1 and HSV-2 viruses are stable after 3 freeze-thaw cycles in UTM, M4, M4RT, M5 and M6 media.

j. Matrix Comparison Study

Since all analytical studies were conducted in the UTM (Universal Transport Media) and clinical studies were conducted using UTM, M4, M4RT, M5 and M6 media, the matrix comparison study was performed. The matrix comparison study was conducted using contrived sample panel made by spiking either HSV-1 or HSV-2 quantitated viral organisms

into each of the recommended media: UTM, M4, M4RT, M5 and M6. Each sample set consisted of 3 replicates spiked at 3×LoD, 3 replicates spiked at 1×10^3 $TCID_{50}$/mL, and 3 replicates spiked at 1×10^5 $TCID_{50}$/mL (9 replicates total for each sample set). Each sample was processed on the InGenius using the HSV 1&2 ELITe MGB Assay. All replicates in all media were detected and showed comparable results.

Target/ Channel	Sample Titer $TCID_{50}$/mL	Sample Matrix					All Media Avg C_T	All Media StDev	All Media %CV
		UTM, Avg C_T	M4, Avg C_T	M4RT, Avg C_T	M5, Avg C_T	M6, Avg C_T			
HSV-2 CH1, FAM	1.00E+05	27.15	26.76	26.42	26.82	27.23	26.88	0.33	1.21%
	1.00E+03	33.86	33.59	33.76	33.51	34.15	33.77	0.25	0.74%
	3×LoD	36.32	35.56	35.96	35.54	36.14	35.91	0.35	0.97%
HSV-1 CH4, AP593	1.00E+05	22.02	21.13	20.82	20.77	20.63	21.08	0.56	2.66%
	1.00E+03	28.01	28.47	27.97	28.58	26.72	27.95	0.74	2.64%
	3×LoD	35.84	36.07	37.02	35.43	34.69	35.81	0.86	2.39%

All tested media showed comparable performance.

k. Reagent Stability

The stability of the HSV 1&2 ELITe MGB Assay was evaluated using several different methods.

Real-time Stability

A real-time stability was completed over a 12 month time period and the data support a shelf-life claim of 10 months for the HSV 1&2 ELITe MGB Assay.

Freeze-thaw Stability

Three lots of HSV 1&2 ELITe MGB Assay reagents were thawed, opened and held for a period of one hour at 30°C and then re-frozen by re-capping and replacing in ≤ -20°C (nominal) freezer. This cycle was repeated 8 times (once per day). Results show that the HSV 1&2 ELITe MGB Assay is stable when subjected to 8 freeze-thaw cycles.

11. Performance Characteristics

a. Reproducibility

The reproducibility of the HSV 1&2 ELITe MGB Assay was evaluated in a multi-site investigation using contrived clinical samples. HSV test panels were prepared by spiking HSV-1 (MacIntyre strain) or HSV-2 (MS strain) virus into UTM media at the concentrations of <1× LoD, 1 × LoD and 3 × LoD. HSV-1 and HSV-2 negative panel members were included as panel member controls. The reproducibility panel composition is shown in the table below:

Name	Description of Contents	Viral Load	Expected Positivity Rate
M1	HSV-1 C_{50} (High Negative) in UTM	<1× LOD	20-80% positive
M2	HSV-1 C_{95} (Low Positive) in UTM	1× LOD	≥95% positive
M3	HSV-1 C_{100} (Moderate Positive) in UTM	2-3 × LOD	100% positive
M4	HSV-2 C_{50} (High Negative) in UTM	<1× LOD	20-80% positive
M5	HSV-2 C_{95} (Low Positive) in UTM	1× LOD	≥95% positive
M6	HSV-2 C_{100} (Moderate Positive) in UTM	2-3 × LOD	100% positive
M7	HSV Negative in UTM	Negative	100% negative

Panels were tested at 3 sites by 2 operators per site with 1 run per operator per day, for 10 non-consecutive days using a single lot of HSV 1&2 ELITe MGB Assay. Testing was performed on a minimum of 90 (30 per site) replicates per panel member for a total of >630 reproducibility samples (minimum 210 per testing site). Lot-to-Lot variability was assessed only at EGI MDx using 3 lots of HSV 1&2 ELITe MGB Assay. Controls were run daily and were included in the first run of the day.

% Agreement, average Cts and %CV for each panel member and per each site are presented in the table below.

		Site – 1			Site – 2			Site – 3				
Target	**Sample**	**% Agreement with Expected Results**	**Avg. Ct**	**Total %CV**	**% Agreement with Expected Results**	**Avg. Ct**	**Total %CV**	**% Agreement with Expected Results**	**Avg. Ct**	**Total %CV**	**% Agreement with Expected Results**	**95% CI**
HSV-1 Result	HSV-1 Low Pos	100.0% (30/30)	38.9	1.70%	100.0% (30/30)	38.3	2.10%	100.0% (30/30)	38	2.00%	100.0% (90/90)	95.9 to 100.0%
	HSV-1 Mod Pos	100.0% (30/30)	36.4	1.30%	100.0% (30/30)	35.5	5.20%	100.0% (30/30)	35.6	1.50%	100.0% (90/90)	95.9 to 100.0%
	HSV-2 Low Pos	100.0% (30/30) [a]	NA	NA	100.0% (29/29) [a]	NA	NA	100.0% (30/30) [a]	NA	NA	100.0% (89/89)	95.6 to 100.0%
	HSV-2 Mod Pos	100.0% (30/30) [a]	NA	NA	100.0% (30/30) [a]	NA	NA	100.0% (30/30) [a]	NA	NA	100.0% (90/90)	95.9 to 100.0%
	HSV Neg	100.0% (60/60) [a]	NA	NA	100.0% (38/38) [a]	41.4	2.50%	100.0% (40/40)	NA	NA	100.0% (138/138)	97.3 to 100.0%
	Pos Control	100.0% (30/30)	27.5	1.30%	100.0% (5/5)	27.5	1.20%	100.0% (5/5)	27	0.80%	100.0% (40/40)	91.2 to 100.0%
	Total Agreement	**100.0% (210/210)**			**100.0% (162/162)**			**100.0% (165/165)**			**100.0% (537/537)**	**98.2 to 100.0%**

[a] Expected Results of HSV-2 Low Positive, HSV-2 Moderate Positive and HSV Negative samples are "Negative" for HSV-1.

		Site – 1			Site – 2			Site – 3				
Target	**Sample**	**% Agreement with Expected Results**	**Avg. Ct**	**Total %CV**	**% Agreement with Expected Results**	**Avg. Ct**	**Total %CV**	**% Agreement with Expected Results**	**Avg. Ct**	**Total %CV**	**% Agreement with Expected Results**	**95% CI**
HSV-2 Result	HSV-1 Low Pos	100.0% (30/30) [b]	NA	NA	100.0% (30/30) [b]	NA	NA	100.0% (30/30) [b]	NA	NA	100.0% (90/90)	95.9 to 100.0%
	HSV-1 Mod Pos	100.0% (30/30) [b]	NA	NA	100.0% (30/30) [b]	NA	NA	100.0% (30/30) [b]	NA	NA	100.0% (90/90)	95.9 to 100.0%
	HSV-2 Low Pos	100.0% (30/30)	36.8	3.10%	100.0% (29/29)	37.8	2.30%	100.0% (30/30)	36.6	1.90%	100.0% (89/89)	95.9 to 100.0%
	HSV-2 Mod Pos	100.0% (30/30)	35.2	1.30%	100.0% (30/30)	35.95	1.60%	100.0% (30/30)	34.6	2.30%	100.0% (90/90)	95.9 to 100.0%
	HSV Neg	100.0% (60/60) [b]	NA	NA	100.0% (38/38) [b]	NA	NA	100.0% (40/40) [b]	NA	NA	100.0% (138/138)	95.9 to 100.0%
	Pos Control	100.0% (30/30)	27	1.30%	100.0% (5/5)	27.4	1.50%	100.0% (5/5)	26.8	1.40%	100.0% (40/40)	95.9 to 100.0%
	Total Agreement	**100.0% (210/210)**			**100.0% (162/162)**			**100.0% (165/165)**			**100.0% (537/537)**	**95.9 to 100.0%**

[b] Expected Results of HSV-1 Low Positive, HSV-1 Moderate Positive and HSV Negative samples are "Negative" for HSV-2.

		Site – 1			Site – 2			Site – 3				
Target	**Sample**	**% Agreement with Expected Results**	**Avg. Ct**	**Total %CV**	**% Agreement with Expected Results**	**Avg. Ct**	**Total %CV**	**% Agreement with Expected Results**	**Avg. Ct**	**Total %CV**	**% Agreement with Expected Results**	**95% CI**
IC Result	HSV-1 Low Pos	100.0% (30/30)	30.4	3.80%	100.0% (30/30)	30.3	2.00%	100.0% (30/30)	30.2	1.70%	100.0% (90/90)	95.9 to 100.0%
	HSV-1 Mod Pos	100.0% (30/30)	30.2	2.30%	100.0% (30/30)	30.4	2.80%	100.0% (30/30)	30.1	0.90%	100.0% (90/90)	95.9 to 100.0%
	HSV-2 Low Pos	100.0% (30/30)	29.9	0.50%	100.0% (29/29)	30.4	2.20%	100.0% (30/30)	30.2	0.60%	100.0% (89/89)	95.9 to 100.0%
	HSV-2 Mod Pos	100.0% (30/30)	29.7	0.80%	100.0% (30/30)	30.4	1.20%	100.0% (30/30)	30.1	0.60%	100.0% (90/90)	95.9 to 100.0%

	HSV Neg	100.0% (60/60)	30.2	1.10%	100.0% (40/40)	30.2	1.90%	100.0% (38/38)	30.1	0.90%	100.0% (138/138)	97.3 to 100.0%
	Pos Control	100.0% (30/30)	29.3	1.40%	100.0% (5/5)	30.2	2.10%	100.0% (5/5)	29.4	0.90%	100.0% (40/40)	91.2 to 100.0%
	Total Agreement	**100.0% (210/210)**			**100.0% (164/164)**			**100.0% (163/163)**			**100.0% (537/537)**	**98.2 to 100.0%**

The highest HSV 1&2 ELITe MGB Assay Site-to-Site variability (as measured by %CV based on Ct values) is 2.19%; the highest Lot-to-Lot is 0.23%, and the highest Operator-to-Operator variability is 0.93% for Moderate Positive panel members.

b. Clinical Performance

To evaluate the clinical performance of the HSV 1&2 ELITe MGB Assay, device performance was compared to a composite reference method. It consisted of an FDA cleared assay and a validated HSV 1&2 PCR followed by bi-directional sequencing of gel electrophoresis-positive samples). Validated HSV 1&2 PCR targeted genomic regions distinct from the HSV 1&2 ELITe MGB Assay. A positive result by the composite reference method is defined as a positive by the FDA cleared PCR or the validated sequencing. Two negative results are needed to confirm a negative)

A total of 1,174 left-over prospectively collected archived swab samples from cutaneous (546) and mucocutaneous (628) lesions from symptomatic patients were collected and evaluated in the study.

The samples were tested with HSV 1&2 ELITe MGB Assay and the Composite Reference Method. Out of the 1,174 tested samples 2 samples were found invalid by the ELITe MGB Assay and were excluded from the performance analysis tables.

Out of the 1172 remaining samples 1 additional invalid sample result for HSV1 and 2 additional invalid sample results for HSV2 by the composite reference method were removed from the performance analysis tables.

Therefore for HSV1, 1171 samples analyzed and for HSV2 1170 samples were analyzed.

HSV-1 Positive/Negative Percent Agreements (PPA/NPA) - Summary of the Results:

The PPA/NPA performance of HSV 1&2 ELITe MGB Assay when compared to the Composite Reference Method in detection of HSV-1 DNA in cutaneous and mucocutaneous lesions is summarized in the table below:

Summary of HSV-1 Results for Valid Cutaneous Lesion Samples (N=545)			
HSV 1&2 ELITe MGB Kit	**Composite reference method**		
	Positive	Negative	Total
Positive	78	7	85
Negative	1	459	460
Total	79	466	545
		95% CI	
PPA	98.7%	93.2-99.8%	
NPA	98.5%	96.9-99.3%	

Summary of HSV-1 Results for Valid Mucocutaneous Lesion Samples (N=626)			
HSV 1&2 ELITe MGB Kit	**Composite reference method**		
	Positive	Negative	Total
Positive	126	12	138
Negative	1	487	488
Total	127	499	626
		95% CI	
PPA	99.2%	95.7-99.9%	
NPA	97.6%	95.8-98.6%	

HSV-2 Positive/Negative Percent Agreements (PPA/NPA) - Summary of the Results:

The PPA/NPA performance of HSV 1&2 ELITe MGB Assay when compared to the Composite Reference Method in detection of HSV-2 DNA in cutaneous and mucocutaneous lesions is summarized in the table below:

Summary of HSV-2 Results for Valid Cutaneous Lesion Samples (N=545)			
HSV 1&2 ELITe MGB Kit	**Composite reference method**		
	Positive	Negative	Total
Positive	125	6	131
Negative	5	409	414
Total	130	415	545
		95% CI	
PPA	96.2%	91.3-98.3%	
NPA	98.6%	96.9-99.3%	

Summary of HSV-2 Results for Valid Mucocutaneous Lesion Samples (N=625)			
HSV 1&2 ELITe MGB Kit	**Composite reference method**		
	Positive	Negative	Total
Positive	164	8	172
Negative	4	449	453
Total	168	457	625
		95% CI	
PPA	97.6%	94.0-99.1%	
NPA	98.2%	96.6-99.1%	

c. **Results: Expected values/Reference Range**

The observed expected values for HSV-1 and HSV-2 in the study population using the HSV 1&2 ELITe MGB Assay were calculated for cutaneous and mucocutaneous specimens and is summarized for the combined sample set per age group, by gender and by specimen source in the tables below. A total number of 6 dual positives for HSV1 and HSV2 detected by the ELITe MGB Assay and one of the samples was confirmed positive by the composite reference method.

Cutaneous and Mucocutaneous HSV 1&2 Prevalence by Age and Gender

Gender	Age Group	Total	HSV 1&2 ELITe MGB Assay HSV-1 results		HSV 1&2 ELITe MGB Assay HSV-2 results	
			Positive	Prevalence	Positive	Prevalence
Female	**<20**	42	18	42.9%	12	28.6%
	20-29	244	68	27.9%	70	28.7%
	30-39	143	24	16.8%	45	31.5%
	40-49	97	14	14.4%	25	25.8%
	50-59	88	18	20.5%	24	27.3%
	≥60	123	21	17.1%	30	24.4%
	All	737	163	22.1%	206	28.0%
Male	**<20**	20	4	20.0%	2	10.0%
	20-29	144	25	17.4%	33	22.9%
	30-39	117	15	12.8%	25	21.4%

	40-49	48	5	10.4%	15	31.3%
	50-59	44	6	13.6%	9	20.5%
	≥60	61	5	8.2%	13	21.3%
	All	434	60	13.8%	97	22.4%
	Gender is not identified	1	0	0%	0	0%
ALL		**1172**	**223**	**19.0%**	**303**	**25.9%**

Cutaneous HSV 1&2 Prevalence by Lesion Source

Lesion Source	Total	HSV 1&2 ELITe MGB Assay HSV-1 results		HSV 1&2 ELITe MGB Assay HSV-2 results	
		Positive	Prevalence	Positive	Prevalence
Genital/Anogenital	248	38	15.3%	78	31.5%
Skin lesion	297	47	15.8%	53	17.8%
Overall	**545**	**85**	**15.6%**	**131**	**24.0%**

Mucocutaneous HSV 1&2 Prevalence by Lesion Source

Lesion Source	Total	HSV 1&2 ELITe MGB Assay HSV-1 results		HSV 1&2 ELITe MGB Assay HSV-2 results	
		Positive	Prevalence	Positive	Prevalence
Genital/Vaginal/Cervical	501	109	21.8%	163	32.5%
Oral	74	21	28.4%	2	2.7%
Other	27	5	18.5%	2	7.4 %
Anorectal	12	2	16.7%	5	41.7%
Urethral	6	0	0 %	0	0 %
Ocular	5	0	0 %	0	0 %
Nasal	2	1	50.0 %	0	0 %
Overall	**627**	**138**	**22.0%**	**172**	**27.4%**

d. HSV-2 Contrived Oral Panel Study

Due to the difficulty in obtaining sufficient HSV-2 positive oral samples, testing for HSV-2 was supplemented by using a contrived panel. The panel consisted of 75 individual negative cheek swab samples collected in UTM and spiked with HSV-2 at concentrations of 3×LoD, 8×LoD, 40×LoD, 200×LoD and 1000×LoD (10 of each), 10 HSV-1 Positive samples spiked at 10×LoD and 15 HSV-1/HSV-2 Negative Oral Samples

All panel members were randomized, blinded to the tester and tested with HSV 1&2 ELITe MGB Assay on the ELITe InGenius instrument according to the clinical study protocol.

The HSV-2 Oral Contrived Panel Study revealed that 49 out of 50 oral HSV-2 contrived samples were positive using HSV 1&2 ELITe MGB Assay (98% detection). All 10 HSV-1 Positive samples confirmed 100% positivity.

Guidance Documents Referenced

FDA Guidance Documents:

1. Evaluating Substantial Equivalence in Premarket Notifications 510(k)
2. Statistical Guidance on Reporting Results from studies evaluating diagnostic tests
3. Guidance Content of Premarket Submissions for Management of Cybersecurity in Medical Devices (DRAFT 10-2-14)
4. Guidance for Clinical Investigators, Sponsors, and IRBs - Adverse Event Reporting to IRBs - Improving Human Subject Protection
5. Guidance for Evaluation and Reporting of Age-, Race-, and Ethnicity-Specific Data in Medical Device Clinical Studies (1500626) (09-12-17)
6. Guidance for Informed Consent for In Vitro Diagnostic Device Studies Using Leftover Human Specimens that are Not Individually Identifiable
7. Guidance for Industry, FDA Reviewers and Compliance on Off-The-Shelf Software Use in Medical Devices
8. Guidance for Refuse to Accept Policy for 510(k)s

CLSI Guidance Documents:

1. EP05-A3 Vol. 34 No. 13 - Evaluation of Precision Performance of Quantitative Measurement Methods; Approved Guideline-Third Edition
2. EP12-A2 Vol. 28 No. 3 - User Protocol for Evaluation of Qualitative Test Performance; Approved Guideline - Second Edition
3. EP17-A2 Vol. 32 No. 8 - Evaluation of Detection Capability for Clinical Laboratory Measurement Procedures; Approved Guideline - Second Edition
4. EP24-A2 Vol. 31 No. 23 - Assessment of the Diagnostic Accuracy of Laboratory Tests Using Receiver Operating Characteristic Curves; Approved Guideline - Second Edition
5. EP25-A Vol. 29 No. 20 - Evaluation of Stability of in Vitro Diagnostic Reagents; Approved Guideline
6. M29-A4 Vol. 34 No. 8 - Protection of Laboratory Workers from Occupationally Acquired Infections; Approved Guideline - 4th Edition
7. MM03 - Molecular Diagnostic Methods for Infectious Diseases; Approved Guideline, 3rd Edition
8. MM06-A2 Vol. 30 No. 22 - Quantitative Molecular Methods for Infectious Diseases; Approved Guideline Second Edition
9. MM09-A2 Vol. 34 No.4 - Nucleic Acid Sequencing Methods in Diagnostic Laboratory Medicine; Approved Guideline
10. MM13-A Vol. 25 No. 31 - Collection, Transport, Preparation, and Storage of Specimens for Molecular Methods; Approved Guideline
11. MM17 Ed 2 Vol. 38 No. 9 - Verification and Validation of Multiplex Nucleic Acid Assays (NATS); Approved Guideline