Date: September 20, 2023

Biokit, S.A.
Àngels Roma
Regulatory Affairs & Design Quality Director
Av. Can Montcau, 7
Llica d'Amunt, Barcelona 08186
Spain

Re: K213987
Trade/Device Name: ARCHITECT HSV-1 IgG, ARCHITECT HSV-1 IgG Calibrator, ARCHITECT HSV-1 IgG Controls
Regulation Number: 21 CFR 866.3305
Regulation Name: Herpes Simplex Virus Serological Assays
Regulatory Class: Class II
Product Code: MXJ
Dated: April 5, 2023
Received: April 7, 2023

Dear Àngels Roma:

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/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Ryan C. Karsner -S

Digitally signed by Ryan C. Karsner -S
Date: 2023.09.20 13:46:31 -04'00'

Ryan Karsner, MD.
Deputy Assistant Director
Hepatitis and General Viral Infections Branch
Division of Microbiology Devices
OHT7: Office of In Vitro Diagnostics
Office of Product Evaluation and Quality
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K213987

Device Name
ARCHITECT HSV-1 IgG

Indications for Use *(Describe)*
The ARCHITECT HSV-1 IgG assay is a chemiluminescent microparticle immunoassay (CMIA) used for the qualitative detection of specific IgG antibodies to herpes simplex virus type 1 (HSV-1) in human serum (collected in serum and serum separator tubes) and plasma (collected in dipotassium EDTA, lithium heparin, and lithium heparin plasma separator tubes) on the ARCHITECT i System.

The ARCHITECT HSV-1 IgG assay is to be used for testing sexually active adults or expectant mothers to aid in the presumptive diagnosis of HSV-1 infection. The test results may not determine the state of active lesions or associated disease manifestations, particularly for primary infection. The predictive value of a reactive or nonreactive result depends on the prevalence of HSV-1 infection in the population and the pre-test likelihood of HSV-1 infection.

NOTE: The performance of the ARCHITECT HSV-1 IgG assay has not been established for use in the pediatric population, for neonatal screening, or for testing immunocompromised or immunosuppressed patients. The assay has not been FDA cleared or approved for screening blood or plasma donors.

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

This 510(k) Summary of Safety and Effectiveness is being submitted in accordance with the requirements of the Safe Medical Device Act of 1990 and 21 CFR 807.92.

1. Submitter's Information	Biokit, S.A. Av. Can Montcau, 7 Lliçà d'Amunt 08186 Barcelona (Spain)

2. Contact Person	Àngels Roma, Regulatory Affairs and Design Quality Director Phone: +34 93 860 90 00 Email: aroma@werfen.com

3. Preparation Date	2023-Sep-20

4. Device Trade Name	ARCHITECT HSV-1 IgG

5. Regulatory Information	Regulation Number	21 CFR 866.3305
	Regulation Description	Herpes simplex virus serological assays.
	Classification	Class II Special Controls
	Product Code	MXJ
	Classification Panel	Microbiology

6. Predicate Device	K000238 (HSV-1 & HSV-2 Differentiation Immunoblot IgG)

7. Indications for Use / Intended Use	The ARCHITECT HSV-1 IgG assay is a chemiluminescent microparticle immunoassay (CMIA) used for the qualitative detection of specific IgG antibodies to herpes simplex virus type 1 (HSV-1) in human serum (collected in serum and serum separator tubes) and plasma (collected in dipotassium EDTA, lithium heparin, and lithium heparin plasma separator tubes) on the ARCHITECT i System. The ARCHITECT HSV-1 IgG assay is to be used for testing sexually active adults or expectant mothers to aid in the presumptive diagnosis of HSV-1 infection. The test results may not determine the state of active lesions or associated disease manifestations, particularly for primary infection. The predictive value of a reactive or nonreactive result depends on the prevalence of HSV-1 infection in the population and the pre-test likelihood of HSV-1 infection. NOTE: The performance of the ARCHITECT HSV-1 IgG assay has not been established for use in the pediatric population, for neonatal screening, or for testing immunocompromised or immunosuppressed patients. The assay has not been FDA cleared or approved for screening blood or plasma donors.

8. Device Description	This assay is an automated, two-step immunoassay for the qualitative detection of specific IgG antibodies to HSV-1 in human serum and plasma using chemiluminescent microparticle immunoassay (CMIA) technology. Sample, HSV-1 specific recombinant gG1 antigen coated paramagnetic microparticles, and assay diluent are combined and incubated. The IgG antibodies to HSV-1 (HSV-1 IgG) present in the sample bind to the HSV-1 specific recombinant gG1 antigen coated microparticles. The mixture is washed. Anti-human IgG acridinium-labeled conjugate is added to create a reaction mixture and incubated. Following a wash cycle, Pre-Trigger and Trigger Solutions are added. The resulting chemiluminescent reaction is measured as a relative light unit (RLU). There is a relationship between the amount of HSV-1 IgG in the sample and the RLU detected by the system optics. The presence or absence of HSV-1 IgG in the sample is determined by comparing the chemiluminescent RLU in the reaction to the cutoff RLU determined from an active calibration.

COMPARISON PREDICATE		
Item	**Predicate**	**New Device**
Trade Names	HSV-1 & HSV-2 Differentiation Immunoblot IgG	ARCHITECT HSV-1 IgG, ARCHITECT HSV-1 IgG Calibrator, ARCHITECT HSV-1 IgG Controls
510K no.	K000238	K213987
Manufacturer	MLR Diagnostics Cypress, CA 90630 -USA	Abbott Ireland Diagnostics Division Finisklin Business Park, Sligo, Ireland
Similarities		
Intended use	MLR Diagnostics' HSV-1 & HSV-2 Differentiation Immunoblot IgG test is intended for qualitatively detecting the presence or absence of human IgG class antibodies to HSV-1 and HSV-2 in human sera. The test is indicated for testing sexually active adults or expectant mothers for aiding in the presumptive diagnosis of HSV-1 and HSV-2 infection. The predictive value of a positive or negative result depends on the population's prevalence and the pretest likelihood of HSV- 1 and HSV-2 infection. The performance of this assay has not been established for use in a pediatric population, for neonatal screening, for testing of immunocompromised patients, for use by a point of care facility or for use with automated equipment	The ARCHITECT HSV-1 IgG assay is a chemiluminescent microparticle immunoassay (CMIA) used for the qualitative detection of specific IgG antibodies to herpes simplex virus type 1 (HSV-1) in human serum (collected in serum and serum separator tubes) and plasma (collected in dipotassium EDTA, lithium heparin, and lithium heparin plasma separator tubes) on the ARCHITECT i System. The ARCHITECT HSV-1 IgG assay is to be used for testing sexually active adults or expectant mothers to aid in the presumptive diagnosis of HSV-1 infection. The test results may not determine the state of active lesions or associated disease manifestations, particularly for primary infection. The predictive value of a reactive or nonreactive result depends on the prevalence of HSV-1 infection in the population and the pre-test likelihood of HSV-1 infection. NOTE: The performance of the ARCHITECT HSV-1 IgG assay has not been established for use in the pediatric population, for neonatal screening, or for testing immunocompromised or

		immunosuppressed patients. The assay has not been FDA cleared or approved for screening blood or plasma donors.
Analyte	Human IgG class antibodies to HSV-1 and HSV-2	IgG antibodies to HSV-1
Regulation Section	21 CFR 866.3305	Same
Classification	Class II Special Controls	Same
Assay Type	Qualitative	Same
Differences		
Product Code	LGC	MXJ
Technology	Nitrocellulose immunoblot	Chemiluminescent immunoassay
Sample type	Human serum	Human serum (collected in serum and serum separator tubes) and plasma (collected in dipotassium EDTA, lithium heparin, and lithium heparin separator tubes)
Result Interpretation	Visually evaluate multiple bands	The cutoff is 1.00 S/CO. <1.00 S/CO = Nonreactive ≥1.00 S/CO = Reactive

9. Performance Summary

Tube Type Matrix Comparison

A total of 62 sets of unique serum samples paired with samples collected in serum separator, dipotassium EDTA plasma, lithium heparin plasma, and lithium heparin plasma separator tubes were evaluated with the ARCHITECT HSV-1 IgG assay on the ARCHITECT i2000SR instrument to support equivalent performance using each of these specimen types.

A weighted Deming regression analysis was performed in the whole assay range and around the cut-off, separately.

The following tube types are acceptable for use with the ARCHITECT HSV-1 IgG assay:

- Serum (serum and serum separator)
- Plasma (dipotassium EDTA, lithium heparin, and lithium heparin separator)

On average, the tube types evaluated showed less than a 10% difference for reactive HSV-1 IgG samples and less than 0.1 S/CO absolute difference for nonreactive HSV-1 IgG samples when compared to the control tube type (serum). The distribution of the percent differences per tube type for reactive samples is listed in the following table.

Tube Types Matrix Comparison Results

Tube Type	Distribution of Absolute % Differences		
	≤ 10%	>10% to ≤20%	>20% to ≤30%
Serum Separator	86.5% (32/37)	8.1% (3/37)	5.4% (2/37)
Dipotassium EDTA	75.7% (28/37)	16.2% (6/37)	8.1% (3/37)
Lithium heparin	83.8% (31/37)	5.4% (2/37)	10.8% (4/37)
Lithium heparin separator	67.6% (25/37)	21.6% (8/37)	10.8% (4/37)

The distribution of the absolute differences (S/CO) per tube type for nonreactive samples is listed in the following table.

Tube Type	Distribution of Absolute Differences (S/CO)		
	≤ 0.1 S/CO	>0.1 to ≤0.2 S/CO	>0.2 to ≤0.3 S/CO
Serum Separator	72.0% (18/25)	20.0% (5/25)	8.0% (2/25)
Dipotassium EDTA	80.0% (20/25)	8.0% (2/25)	12.0% (3/25)
Lithium heparin	72.0% (18/25)	20.0% (5/25)	8.0% (2/25)
Lithium heparin separator	76.0% (19/25)	8.0% (2/25)	16.0% (4/25)

Study results support the use of the above-mentioned blood collection tubes with the ARCHITECT HSV-1 IgG assay for serum and plasma.

Precision

Within-Laboratory Precision (20-Day)

A within-laboratory precision study was performed according to CLSI EP05-A3. Testing was conducted using 3 lots of the ARCHITECT HSV-1 IgG reagents, 3 lots of the ARCHITECT HSV-1 IgG Calibrator, 1 lot of the ARCHITECT HSV-1 IgG Controls, and 1 ARCHITECT i2000SR instrument. Two controls, 3 human serum panel samples, and 3 human plasma panel samples were tested in a minimum of 2 replicates at 2 separate times per day on 20 days on 3 reagent lot/calibrator lot combinations, where a unique reagent lot and a unique calibrator lot were paired.

The precision of the ARCHITECT HSV-1 IgG assay was considered acceptable if the within-laboratory (total) imprecision (within-run, between-run, and between-day) was less than or equal to 0.07 S/CO for samples less than 1.00 S/CO and less than or equal to 7.5 %CV for samples greater than 1.00 S/CO.

The performance of 1 representative lot of the ARCHITECT HSV-1 IgG reagents is shown in the following table.

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Precision Results

Sample	n	Mean (S/CO)	Within-Run (Repeatability)		Within-Laboratory[a]	
			SD	%CV	SD	%CV
Negative Control	80	0.32	0.008	N/A	0.009	N/A
Positive Control	80	3.11	0.082	2.63	0.082	2.65
Serum Panel 1	80	1.12	0.030	2.69	0.035	3.08
Serum Panel 2	80	1.59	0.043	2.68	0.047	2.97
Serum Panel 3	80	2.54	0.063	2.48	0.065	2.58
Plasma Panel 1	80	1.14	0.057	5.00	0.059	5.23
Plasma Panel 2	80	1.58	0.035	2.19	0.040	2.54
Plasma Panel 3	80	2.92	0.065	2.23	0.078	2.68

N/A = Not applicable

[a]Includes within-run, between-run, and between-day variability.

Within-Laboratory Precision (12-Day)

An additional within-laboratory precision study was conducted using samples with higher analyte levels, using 2 lots of the ARCHITECT HSV-1 IgG reagents, 1 lot of the ARCHITECT HSV-1 IgG Calibrator, and 1 instrument. Two human serum panels and 2 human plasma panels were tested in replicates of 2 at 2 separate times per day on 12 different days.

Sample	n	Mean (S/CO)	Within-Run (Repeatability)		Between-Lot		Within-Laboratory[a]	
			SD	%CV	SD	%CV	SD	%CV
Serum Panel 4	96	7.99	0.299	3.7	0.040	0.5	0.325	4.1
Serum Panel 5	96	15.27	0.606	4.0	0.169	1.1	0.754	4.9
Plasma Panel 4	96	7.68	0.333	4.3	0.220	2.9	0.406	5.3
Plasma Panel 5	96	19.17	0.758	4.0	0.109	0.6	0.913	4.8

[a]Includes within-run, between-run, between-day, and between-lot variability.

Reproducibility

A reproducibility study was performed based on guidance from CLSI EP05-A3. Testing was conducted at each of 3 testing sites using 1 lot of the ARCHITECT HSV-1 IgG reagents, 1 lot of the ARCHITECT HSV-1 IgG Calibrator, 1 lot of the ARCHITECT HSV-1 IgG Controls, and 1 instrument. Two controls, 3 human serum panel samples, and 3 human plasma panel samples were tested in 3 replicates at 2 separate times per day on 5 different days.

Reproducibility Results

			Repeatability		**Between-Run**		**Between-Day**		**Between-Site/Instrument**		**Reproducibility[a]**	
Sample	**n**	**Mean (S/CO)**	**SD**	**%CV**	**SD**	**%CV**	SD	%CV	SD	%CV	**SD**	**%CV**
Negative Control	90	0.35	0.01	N/A	0.00	N/A	0.00	N/A	0.01	N/A	0.02	N/A
Positive Control	90	3.28	0.09	2.8	0.01	0.2	0.03	0.8	0.07	2.1	0.12	3.7
Serum Panel 1	90	1.10	0.04	3.3	0.01	1.2	0.00	0.0	0.04	3.7	0.06	5.1
Serum Panel 2	90	1.63	0.04	2.6	0.00	0.0	0.00	0.0	0.04	2.4	0.06	3.6
Serum Panel 3	90	2.46	0.07	2.8	0.00	0.0	0.00	0.0	0.07	2.7	0.10	3.9
Plasma Panel 1	90	1.10	0.03	3.0	0.01	0.9	0.00	0.0	0.03	3.0	0.05	4.3
Plasma Panel 2	90	1.55	0.06	3.8	0.00	0.0	0.00	0.0	0.00	0.0	0.06	3.8
Plasma Panel 3	90	2.83	0.08	2.8	0.03	0.9	0.00	0.0	0.11	3.9	0.14	4.9

[a]Includes repeatability (within-run), between-run, between-day, and between-instrument/site variability.

Analytical Specificity

Interference

Potentially Interfering Endogenous Substances and Potentially Interfering Drugs

The ARCHITECT HSV-1 IgG assay was evaluated for potential interference of endogenous and exogenous (drugs) substances using HSV-1 IgG negative and low reactive samples. Studies were

performed based on guidance from CLSI EP07, 3rd ed. Each substance was tested at 2 levels of the analyte, nonreactive and reactive (target ranges: 0.60 to 0.85 S/CO and 1.20 to 2.00 S/CO, respectively) using 12 replicates for each negative and low reactive HSV-1 IgG sample.

Less than 10% absolute difference for reactive HSV-1 IgG samples and less than 0.10 S/CO absolute difference for negative HSV-1 IgG samples were observed at the following concentrations of potentially interfering substances.

Potentially Interfering Endogenous Substances

Potentially Interfering Endogenous Substance	Potential Interferent Concentration	
	Default Units	Alternate Units
Bilirubin (Conjugated)	40 mg/dL	475 µmol/L
Bilirubin (Unconjugated)	40 mg/dL	684 µmol/L
Hemoglobin	1000 mg/dL	10 g/L
Triglycerides	1500 mg/dL	16.94 mmol/L
Total Protein	15 g/dL	150 g/L
Serum Albumin	6 g/dL	60 g/L
Total Cholesterol	400 mg/dL	10.3 mmol/L

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Potentially Interfering Drugs

Potentially Interfering Drug	Potential Interferent Concentration	
	Default Units	Alternate Units
Acetaminophen	15.6 mg/dL	1030 µmol/L
Acetylsalicylic acid	3.00 mg/dL	167 µmol/L
Acyclovir	6.6 mg/dL	293 µmol/L
Ampicillin	7.5 mg/dL	215 µmol/L
Ascorbic acid	5.25 mg/dL	298 µmol/L
Biotin	4250 ng/mL	17.3 µmol/L
Calcium dobesilate	6.00 mg/dL	144 µmol/L
Cefoxitin	660 mg/dL	15 500 µmol/L
Cyclosporine	0.180 mg/dL	1.50 µmol/L
Doxycycline	1.80 mg/dL	40.5 µmol/L
Famvir	0.25 mg/L	0.778 µmol/L
Ibuprofen	21.9 mg/dL	1060 µmol/L
Levodopa	0.750 mg/dL	38.0 µmol/L
Methyldopa	2.25 mg/dL	107 µmol/L
Metronidazole	12.3 mg/dL	719 µmol/L
N-Acetylcysteine	15.0 mg/dL	920 µmol/L
Phenylbutazone	32.1 mg/dL	1040 µmol/L
Rifampicin	4.8 mg/dL	58.3 µmol/L
Sodium heparin	330 units/dL	N/A
Theophylline	6.00 mg/dL	333 µmol/L
Valacyclovir	3 mg/L	8.314 µmol/L

Potential Cross-Reactivity

The ARCHITECT HSV-1 IgG assay was evaluated for potential cross-reactivity using specimens from individuals containing antibodies to other microorganisms or with medical conditions unrelated to HSV-1 infection. Specimens confirmed negative for HSV-1 IgG by a comparator method (immunoblot) were evaluated with the ARCHITECT HSV-1 IgG assay.

The data are summarized in the following table.

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Cross Reactivity Study Performance Results

Category	n	ARCHITECT HSV-1 IgG		False Positive Rate (%)
		Reactive	Nonreactive	
Anti-dsDNA Autoantibodies	8	2	6	25
Antinuclear Antibody (ANA)	11	0	11	0
Candida albicans	12	0	12	0
Chlamydia trachomatis	12	0	12	0
Cytomegalovirus (CMV) IgG	13	0	13	0
Elevated IgG	10	0	10	0
Elevated IgM	8	0	8	0
Epstein-Barr virus (EBV) IgG	14	0	14	0
Gardnerella vaginalis	10	0	10	0
HAMA	8	0	8	00
Hepatitis A virus (HAV) IgG	11	0	11	0
Hepatitis B virus (HBV) IgG	12	0	12	0
Hepatitis C virus (HCV) IgG	11	0	11	0
HSV-2 IgG	13	0	13	0
Human-Herpesvirus-6 IgG	14	0	14	0
Human-Herpesvirus-8 IgG	5	1	4	20

Category	n	ARCHITECT HSV-1 IgG		False Positive Rate (%)
		Reactive	Nonreactive	
Human immunodeficiency virus IgG	12	0	12	0
Human papillomavirus (HPV) IgG	10	1	9	10
Monoclonal hyperimmunoglobulinemia	12	0	12	0
Mycoplasma pneumoniae	5	0	5	0
Neisseria gonorrhea	8	0	8	0
Parvovirus B19 IgG	14	0	14	0
Rheumatoid Factor (RF)	10	1	9	10
Rubella virus IgG	11	0	11	0
Streptococcus	7	1	6	14
Toxoplasma gondii	11	0	11	0
Treponema pallidum	11	0	11	0
Varicella-zoster virus (VZV) IgG	11	0	11	0

CDC Panel Agreement

The CDC Performance Panel was obtained from the Centers for Disease Control and Prevention (CDC) and tested using the ARCHITECT HSV-1 IgG assay. The panel consisted of 2 aliquots each of 50 serum samples with unknown HSV-1 status for a total of 100. The results were submitted to the CDC for data evaluation and do not imply endorsement of the assay by the CDC.

The ARCHITECT HSV-1 IgG assay demonstrated 100% positive percent agreement (PPA) for reactive samples (46/46) and 100% negative percent agreement (NPA) for nonreactive samples (54/54) when evaluating the CDC panel.

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Clinical Agreement Study

A multi-center clinical study was conducted to evaluate the clinical performance of the ARCHITECT HSV-1 IgG assay. Sensitivity and specificity were estimated using PPA and NPA as determined by comparing the performance of the ARCHITECT HSV-1 IgG assay to a composite comparator method comprised of a commercially available anti-HSV-1 IgG immunoblot method (comparator assay) and a Western Blot reference confirmatory test (University of Washington, Seattle).

A total of 915 specimens, which included sexually active individuals and pregnant females, were collected prospectively within the US and tested at 3 independent external laboratories.

The PPA and NPA results are summarized in the following tables.

Clinical Performance of the ARCHITECT HSV-1 IgG Assay in the Sexually Active Population

		Composite Comparator Assay		
		Positive	**Equivocal**	**Negative**
ARCHITECT HSV-1 IgG	**Reactive**	426	0	6
	Nonreactive	25	0	161
	Total	451	0	167
		PPA= 94.46% (426/451); **95% CI**= 91.95% to 96.22%		**NPA**= 96.41% (161/167); **95% CI**= 92.38% to 98.34%

Clinical Performance of the ARCHITECT HSV-1 IgG Assay in the Pregnant Population

		Composite Comparator Assay		
		Positive	**Equivocal**	**Negative**
ARCHITECT HSV-1 IgG	**Reactive**	197	0	0
	Nonreactive	8	0	92
	Total	205	0	92
		PPA= 96.10% (197/205); **95% CI**= 92.49% to 98.01%		**NPA**= 100.00% (92/92); **95% CI**= 95.99% to 100.00%

10.Stability

The stability studies data support the following storage conditions for the ARCHITECT HSV-1 IgG assay:

Stability Study	Claims
Reagent On-Board	Up to 30 days
Reagent Unopened Shelf Life	12 months at 2-8°C
Reagent In-Use/Opened	12 months at 2-8ºC
Calibrator Unopened Shelf-Life	12 months at 2-8°C
Calibrator In-Use/Opened	12 months at 2-8ºC
Controls Unopened Shelf Life	12 months at 2-8°C
Controls In-Use/Opened	12 months at 2-8ºC

11.Conclusion

The analytical and clinical study results demonstrate that the ARCHITECT HSV-1 IgG is substantially equivalent to the predicate device, HSV-1 & HSV-2 Differentiation Immunoblot IgG (FDA cleared under K000238), and that the assay is safe and effective for its labeled intended use.