Date: February 12, 2025

Biokit, S.A.
Janna Puig
Regulatory Affairs Manager
Av. Can Montcau 7
Lliçà d'Amunt, Barcelona, 08186
Spain

Re: K243575
Trade/Device Name: ARCHITECT HSV-2 IgG, ARCHITECT HSV-2 IgG Calibrator, ARCHITECT HSV-2 IgG Controls
Regulation Number: 21 CFR 866.3305
Regulation Name: Herpes Simplex Virus Serological Assays
Regulatory Class: Class II
Product Code: MYF
Dated: November 19, 2024
Received: November 19, 2024

Dear Janna Puig:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

JORGE L. MUNOZ -S

Digitally signed by JORGE L. MUNOZ -S
Date: 2025.02.12 15:35:57 -04'00'

Jorge Munoz, Ph.D.
Deputy Branch Chief
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)*
K243575

Device Name
ARCHITECT HSV-2 IgG

Indications for Use *(Describe)*
The ARCHITECT HSV-2 IgG assay is a chemiluminescent microparticle immunoassay (CMIA) used for the qualitative detection of specific IgG antibodies to herpes simplex virus type 2 (HSV-2) 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-2 IgG assay is to be used for testing sexually active adults or expectant mothers to aid in the presumptive diagnosis of HSV-2 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-2 infection in the population and the pre-test likelihood of HSV-2 infection.

NOTE: The performance of the ARCHITECT HSV-2 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	Janna Puig, Regulatory Affairs Manager Phone: +34 93 860 90 00 Email: jpuig@werfen.com

3. Preparation Date	2025-02-12

4. Device Trade Name	ARCHITECT HSV-2 IgG

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

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

7. Indications for Use / Intended Use	The ARCHITECT HSV-2 IgG assay is a chemiluminescent microparticle immunoassay (CMIA) used for the qualitative detection of specific IgG antibodies to herpes simplex virus type 2 (HSV-2) 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-2 IgG assay is to be used for testing sexually active adults or expectant mothers to aid in the presumptive diagnosis of HSV-2 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-2 infection in the population and the pre-test likelihood of HSV-2 infection. NOTE: The performance of the ARCHITECT HSV-2 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	The ARCHITECT HSV-2 IgG assay is an automated, two-step immunoassay for the qualitative detection of IgG antibodies to HSV-2 in human serum and plasma using chemiluminescent microparticle immunoassay (CMIA) technology. The kit contains different components: Reagent (microparticles, conjugate and assay diluent), Calibrator, and external Controls (reactive and nonreactive).

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COMPARISON PREDICATE		
Item	**Predicate**	**New Device**
Trade Names	HSV-1 & HSV-2 Differentiation Immunoblot IgG	ARCHITECT HSV-2 IgG, ARCHITECT HSV-2 IgG Calibrator, ARCHITECT HSV-2 IgG Controls
510K no.	K000238	K243575
Manufacturer	MRL Diagnostics Cypress, CA 90630 -USA	Abbott Ireland Diagnostics Division Finisklin Business Park, Sligo, Ireland
Similarities		
Intended use	MRL 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 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	The ARCHITECT HSV-2 IgG assay is a chemiluminescent microparticle immunoassay (CMIA) used for the qualitative detection of specific IgG antibodies to herpes simplex virus type 2 (HSV- 2) 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-2 IgG assay is to be used for testing sexually active adults or expectant mothers to aid in the presumptive diagnosis of HSV-2 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

	of care facility or for use with automated equipment.	depends on the prevalence of HSV-2 infection in the population and the pre-test likelihood of HSV-2 infection. NOTE: The performance of the ARCHITECT HSV-2 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.
Measurand	Human IgG class antibodies to HSV-1 and HSV-2	Human IgG antibodies to HSV-2
Regulation Section	21 CFR 866.3305	Same
Classification	Class II Special Controls	Same
Assay Type	Qualitative	Same
Differences		
Product Code	LGC	MYF
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 plasma 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

Interpretation of results

The cutoff is 1.00 S/CO.
The ARCHITECT HSV-2 IgG test result should be used in conjunction with information available from clinical evaluation and other diagnostic procedures.

S/CO	Interpretation
< 1.00	Nonreactive
≥ 1.00	Reactive

Specimen Collection Types

Sixty-one (61) sets of unique serum samples paired with samples collected in serum separator tube (SST), dipotassium EDTA plasma, lithium-heparin plasma and lithium heparin plasma separator tube (PST) were evaluated with the ARCHITECT HSV-2 IgG assay on the ARCHITECT i2000SR instrument to support equivalent performance using each of these specimen types. The samples were analyzed by linear regression using serum as comparator matrix as shown in the table below:

Tube (y) vs. Serum (x)	Regression Equation	Sample Interval	N[a]	r[b]
Serum separator tube	y = 1.03x – 0.0350 S/CO	0.50-54.76 S/CO	61	0.998
Plasma, dipotassium EDTA	y = 1.02x + 0.0079 S/CO	0.56-54.02 S/CO	61	0.997
Plasma, lithium heparin	y = 1.03x – 0.0029 S/CO	0.55-54.77 S/CO	61	0.996
Plasma, lithium heparin separator	y = 1.00x + 0.0343 S/CO	0.56-54.55 S/CO	61	0.997

[a]Number of samples tested
[b]Correlation coefficient

The following tube types are acceptable for use with the ARCHITECT HSV-2 IgG assay:

- Serum
- Serum separator
- Plasma (dipotassium EDTA, lithium heparin, lithium heparin separator).

Precision

a. Within-Laboratory Precision (20-Day)

A within-laboratory precision study was performed using 3 lots of the ARCHITECT HSV-2 IgG reagents, 3 lots of the ARCHITECT HSV-2 IgG Calibrator, 1 lot of the

ARCHITECT HSV-2 IgG Controls, and 1 ARCHITECT i2000SR instrument. The 20-Day within laboratory precision data is shown in the following table.

Table 1. 20-Day Within-Laboratory Precision

		Mean	Within-Run (Repeatability)		Between-Lot[a]		Within-Laboratory[b]	
Sample	**n**	**(S/CO)**	**SD**	**%CV**	**SD**	**%CV**	**SD**	**%CV**
Negative Control	240	0.30	0.009	N/A	0.007	N/A	0.012	N/A
Positive Control	240	3.01	0.075	2.5	0.081	2.7	0.117	3.9
Serum Panel 1	240	0.95	0.029	N/A	0.015	N/A	0.040	N/A
Serum Panel 2	240	1.60	0.037	2.3	0.096	6.0	0.109	6.8
Serum Panel 3	244[c]	2.47	0.093	3.7	0.270	10.9	0.286	11.6
Plasma Panel 1	240	1.03	0.028	2.7	0.004	0.4	0.034	3.3
Plasma Panel 2	240	1.81	0.047	2.6	0.089	4.9	0.103	5.7
Plasma Panel 3	240	2.91	0.071	2.4	0.093	3.2	0.126	4.3

N/A = Not applicable

[a] Calibrator and reagent lots are confounded.

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

[c] Serum Panel 3 was tested for one additional day.

b. 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-2 IgG reagents, 1 lot of the ARCHITECT HSV-2 IgG Calibrator, and 1 ARCHITECT i2000SR instrument.

Table 2. 12-Day Within-Laboratory Precision

			Within-Run (Repeatability)		Between-Lot		Within-Laboratory[a]	
Sample	**n**	**Mean (S/CO)**	**SD**	**%CV**	**SD**	**%CV**	**SD**	**%CV**
Serum Panel 4	96	7.14	0.274	3.8	0.125	1.7	0.372	5.2
Serum Panel 5	96	14.73	0.519	3.5	0.099	0.7	0.680	4.6
Plasma Panel 4	96	7.85	0.312	4.0	0.000	0.0	0.354	4.5

Plasma Panel 5	96	14.90	0.578	3.9	0.000	0.0	0.745	5.0

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

Reproducibility

A reproducibility study was conducted at 3 testing sites using one lot of the ARCHITECT HSV-2 IgG reagents, 1 lot of the ARCHITECT HSV-2 IgG Calibrator, 1 lot of the ARCHITECT HSV-2 IgG controls, and 1 ARCHITECT i2000SR instrument, over 5 days.

Table 3. Reproducibility

		Mean	Repeatability		Between-Run		Between-Day		Between-Site/Instrument		Reproducibility[a]	
Sample	**n**	**(S/CO)**	**SD**	**%CV**	**SD**	**%CV**	**SD**	**%CV**	**SD**	**%CV**	**SD**	**%CV**
Negative Control	90	0.29	0.01	N/A	0.00	N/A	0.00	0.9	0.01	4.8	0.02	N/A
Positive Control	90	2.98	0.07	2.3	0.04	1.2	0.04	1.4	0.13	4.3	0.16	5.2
Serum Panel 1	90	0.89	0.02	N/A	0.01	N/A	0.01	1.4	0.02	2.4	0.04	N/A
Serum Panel 2	90	1.56	0.05	3.5	0.00	0.0	0.01	0.7	0.03	2.0	0.06	4.0
Serum Panel 3	90	2.52	0.06	2.2	0.03	1.3	0.02	1.0	0.08	3.3	0.11	4.3
Plasma Panel 1	90	0.96	0.03	N/A	0.01	N/A	0.02	1.7	0.03	3.5	0.05	N/A
Plasma Panel 2	90	1.76	0.05	2.8	0.00	0.0	0.03	1.7	0.07	4.0	0.09	5.2
Plasma Panel 3	90	2.82	0.09	3.3	0.00	0.0	0.00	0.0	0.12	4.3	0.15	5.4

[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-2 IgG assay was evaluated for potential interference of endogenous and exogenous (drugs) substances using HSV-2 IgG nonreactive and low reactive samples.

Less than 10% absolute difference for reactive HSV-2 IgG samples and less than 0.10 S/CO absolute difference for nonreactive HSV-2 IgG samples were observed at the following concentrations of potentially interfering substances.

Table 4. 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

Table 5. Potentially Interfering Drugs

	Potential Interferent Concentration	
Potentially Interfering Drug	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

	Potential Interferent Concentration	
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-2 IgG assay was evaluated for potential cross-reactivity using specimens from individuals containing antibodies to other microorganisms or with medical conditions unrelated to HSV-2 infection. When testing with the ARCHITECT HSV-2 IgG assay:

- Out of 8 specimens with Anti-dsDNA autoantibodies, 1 resulted in false reactive result.
- Out of 12 specimens with elevated IgG, 1 resulted in false reactive result.
- Out of 10 *Gardnerella vaginalis specimens,* 1 resulted in false reactive result.
- Out of 13 Human herpesvirus-6 IgG specimens, 1 resulted in false reactive result.
- Out of 10 Human herpesvirus-8 IgG specimens, 2 resulted in false reactive result.

- Out of 13 Parvovirus B19 IgG, 2 resulted in false reactive results.
- Out of 10 RF specimens, 1 resulted in false reactive result.
- Out of 10 *Toxoplasma gondii* specimens, 1 resulted in false reactive result.

The data are summarized in the following table.

Table 6. Potential Cross-Reactivity

Category	n	ARCHITECT HSV-2 IgG		False Positive Rate (%)
		Reactive	Nonreactive	
Anti-dsDNA autoantibodies	8	1	7	12.50
Antinuclear antibody (ANA)	12	0	12	0
Candida albicans	13	0	13	0
Chlamydia trachomatis	10	0	10	0
Cytomegalovirus (CMV) IgG	11	0	11	0
Elevated IgG	12	1	11	8.33
Elevated IgM	9	0	9	0
Epstein-Barr virus (EBV) IgG	12	0	12	0
Gardnerella vaginalis	10	1	9	10.00
HAMA	8	0	8	0
Hepatitis A virus (HAV) IgG	10	0	10	0
Hepatitis B virus (HBV) IgG	12	0	12	0
Hepatitis C virus (HCV) IgG	12	0	12	0
HSV-1 IgG	6	0	6	0
Human herpesvirus-6 IgG	13	1	12	7.69
Human herpesvirus-8 IgG	10	2	8	20.00
Human immunodeficiency virus (HIV) IgG	11	0	11	0
Human papillomavirus (HPV) IgG	12	0	12	0
Monoclonal hyperimmunoglobulinemia	13	0	13	0
Multiparous females (≥ 2 full-term pregnancies)	3	0	3	0
Mycoplasma pneumoniae	5	0	5	0

Category	n	ARCHITECT HSV-2 IgG		False Positive Rate (%)
		Reactive	Nonreactive	
Neisseria gonorrhea	6	0	6	0
Parvovirus B19 IgG	13	2	11	15.38
Pregnant females (all trimesters)	6	0	6	0
Rheumatoid Factor (RF)	10	1	9	10.00
Rubella virus IgG	12	0	12	0
Streptococcus	9	0	9	0
Toxoplasma gondii	10	1	9	10.00
Treponema pallidum	12	0	12	0
Varicella-zoster virus (VZV) IgG	13	0	13	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-2 IgG assay. The CDC panel consisted of 2 aliquots each of 50 serum samples with unknown HSV-2 status for a total of 100 blind characterized samples. The results were submitted to the CDC for data evaluation and do not imply endorsement of the assay by the CDC.

The ARCHITECT HSV-2 IgG assay demonstrated 100% Positive Percent Agreement (PPA) for reactive samples (30/30) and 97.14% Negative Percent Agreement (NPA) for nonreactive samples (68/70) when evaluating the CDC performance panel.

Cut-off

A study to establish the ARCHITECT HSV-2 IgG assay cutoff was performed using 505 serum samples (271 reactive, 228 nonreactive, and 6 equivocal for HSV-2 IgG antibodies).

A Receiver-Operating Characteristic (ROC) curve analysis was performed. The optimal cut-off of 1.00 S/CO was selected and validated in the method comparison study.

Carry-Over

The ARCHITECT HSV-2 IgG assay is not susceptible to within-assay sample carryover.

Expected Values

Representative performance data are provided in this section. Results obtained in individual laboratories may vary considering HSV prevalence. The prevalence may vary depending upon geographical location, age, sex, type of test employed, specimen collection and handling procedures as well as clinical history of the patient.

It is recommended that each laboratory determine its own reference range based upon its particular local and population characteristics.

Clinical performance of the ARCHITECT HSV-2 IgG assay was evaluated with 915 samples collected prospectively from individuals from the intended use population. Of the 915 individuals, there were 670 (73%) females and 245 (27%) males. The median age was 35 years (age range: 14 to 99 years). Testing of the specimens was performed at 3 clinical testing sites.

Table 7. Distribution of HSV-2 IgG reactive and nonreactive results by age and sex.

Age Range (Years)	Sex	n	ARCHITECT HSV-2 IgG Result	
			Number of Reactive (%)	Number of Nonreactive (%)
14 to 20	Female	45	14 (31%)	31 (69%)
	Male	6	1 (17%)	5 (83%)
21 to 30	Female	242	49 (20%)	193 (80%)
	Male	49	11 (22%)	38 (78%)
31 to 40	Female	181	66 (36%)	115 (64%)
	Male	40	10 (25%)	30 (75%)
41 to 50	Female	72	39 (54%)	33 (46%)
	Male	36	12 (33%)	24 (67%)
51 to 60	Female	46	24 (52%)	22 (48%)
	Male	43	16 (37%)	27 (63%)
61 to 70	Female	33	23 (70%)	10 (30%)
	Male	32	16 (50%)	16 (50%)
71 to 99	Female	51	25 (49%)	26 (51%)
	Male	39	10 (26%)	29 (74%)

Total	Female	670	240 (36%)	430 (64%)
	Male	245	76 (31%)	169 (69%)
	Overall	915	316 (35%)	599 (65%)

Clinical Agreement Study

A multi-center clinical study was conducted to evaluate the clinical performance of the ARCHITECT HSV-2 IgG assay. Positive Percent Agreement (PPA) and Negative Percent Agreement (NPA) were determined by comparing the performance of the ARCHITECT HSV-2 IgG assay to a composite comparator method of 3 commercially available anti-HSV-2 IgG assays where a 2 out of 3 approach was followed to determine the final composite comparator method result.

A total of 915 specimens, which included sexually active individuals and pregnant females, were collected prospectively within the United States and tested at 3 independent external laboratories. The PPA and NPA results are summarized in the following tables.

Table 8. Clinical Performance of the ARCHITECT HSV-2 IgG Assay in the Sexually Active Population

		Composite Comparator Method		
		Positive	**Equivocal**	**Negative**
ARCHITECT HSV-2 IgG	**Reactive**	223	0	12
	Nonreactive	5	3	375
	Total	228	3	387
		PPA= 96.54% (223/231); **95% CI**= 93.32% to 98.24%		**NPA**= 96.90% (375/387); **95% CI**= 94.66% to 98.22%

Table 9. Clinical Performance of the ARCHITECT HSV-2 IgG Assay in the Pregnant Population.

		Composite Comparator Method		
		Positive	**Equivocal**	**Negative**
ARCHITECT HSV-2 IgG	**Reactive**	78	0	3
	Nonreactive	4	0	212
	Total	82	0	215
		PPA= 95.12% (78/82); **95% CI**= 88.12% to 98.09%		**NPA**= 98.60% (212/215); **95% CI**= 95.98% to 99.52%

10. Stability

The data support the following storage conditions for the ARCHITECT HSV-2 IgG assay:

Table 10. ARCHITECT HSV-2 IgG storage conditions

Stability Study	Claims
Reagent On-Board	Up to 30 days
Reagent Unopened Shelf Life	10 months at 2-8°C
Reagent In-Use/Opened	10 months at 2-8°C
Calibrator Unopened Shelf-Life	12 months at 2-8°C
Calibrator In-Use/Opened	12 months at 2-8°C
Controls Unopened Shelf Life	12 months at 2-8°C
Controls In-Use/Opened	12 months at 2-8°C

11. Conclusion

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.