October 27, 2022

Abbott Laboratories
Shannon Reibling
Regulatory Affairs Project Manager
Dept 09AA, Bldg. AP8A, 100 Abbott Park Rd.
Abbott Park, Illinois 60064

Re: K220949
Trade/Device Name: Architect CMV IgG
Regulation Number: 21 CFR 866.3175
Regulation Name: Cytomegalovirus Serological Reagents
Regulatory Class: Class II
Product Code: LFZ
Dated: March 31, 2022
Received: April 1, 2022

Dear Shannon Reibling:

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,

Maria Garcia, Ph.D.
Assistant Director
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)*

Device Name
ARCHITECT CMV IgG
ARCHITECT CMV IgG Calibrators
ARCHITECT CMV IgG Controls

Indications for Use *(Describe)*
ARCHITECT CMV IgG

The ARCHITECT CMV IgG assay is a chemiluminescent microparticle immunoassay (CMIA) used for the qualitative detection of IgG antibodies to cytomegalovirus in human serum, serum separator, and plasma tubes (lithium heparin, lithium heparin separator, and tripotassium EDTA) on the ARCHITECT i System.

The ARCHITECT CMV IgG assay is to be used as an aid in the diagnosis of infection with cytomegalovirus and as an aid in the determination of serological status to cytomegalovirus in individuals including women of child-bearing age.

The ARCHITECT CMV IgG assay has not been cleared for use in screening blood, plasma, or tissue donors.

ARCHITECT CMV IgG Calibrators

The ARCHITECT CMV IgG Calibrators are for the calibration of the ARCHITECT i System when used for the qualitative detection of IgG antibodies to cytomegalovirus in human serum and plasma.

ARCHITECT CMV IgG Controls

The ARCHITECT CMV IgG Controls are for the estimation of test precision and the detection of systematic analytical deviations of the ARCHITECT i System when used for the qualitative detection of IgG antibodies to cytomegalovirus in human serum and plasma.

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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## Section 5: 510(k) Summary (Summary of Safety and Effectiveness)

This summary of the 510(k) safety and effectiveness information is submitted in accordance with the requirements of SMDA 1990 and 21 CFR § 807.92.

### I. Applicant Name

Abbott Diagnostics
Department 09AA, Building AP8A,
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Primary contact person for all communications:

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## II. Device Name

ARCHITECT CMV IgG

Reagents

Trade Name: ARCHITECT CMV IgG Reagent Kit
Device Classification: Class II
Classification Name: Cytomegalovirus serological reagents
Governing Regulation: 21 CFR § 866.3175
Code: LFZ

Calibrator

Trade Name: ARCHITECT CMV IgG Calibrator
Device Classification: Class II, 510(k) Exempt
Classification Name: Calibrator
Governing Regulation: 21 CFR § 862.1150
Code: JIT

Controls

Trade Name: ARCHITECT CMV IgG Controls
Device Classification: Class I, 510(k) Exempt
Classification Name: Control
Governing Regulation: 21 CFR § 862.1660
Code: JJX

## III. Predicate Device

ADVIA Centaur CMV IgG Assay (K181213)

## IV. Description of Device

Reagents

The ARCHITECT CMV IgG reagent kit contains:

- **Microparticles:** (1 bottle x 6.6 mL per 100-test / 1 bottle x 27.0 mL per 500-test) CMV virus lysate (strain AD169) coated microparticles in TRIS buffered saline with protein (bovine). Minimum concentration: 0.08% solids. Preservatives: ProClin 300 and antimicrobial agents.

- **Conjugate:** (1 bottle x 5.9 mL per 100-test / 1 bottle x 26.3 mL per 500-test). Murine anti-human IgG acridinium-labeled conjugate in MES buffer with protein (bovine). Minimum concentration: 44 ng/mL. Preservatives: sodium azide and antimicrobial agents.

- **Assay Diluent:** (1 bottle x 10.0 mL per 100-test / 1 bottle x 50.9 mL per 500-test). Calf serum and MES buffer with protein (bovine). Preservatives: ProClin 300 and ProClin 950.

Calibrators

The ARCHITECT CMV IgG Calibrators:

- Calibrator A - 1 Bottle (4.0 mL): contains recalcified human plasma with protein (ovine) stabilizer. Preservative: sodium azide.

- Calibrators B through F - 5 bottles (4.0 mL each): contain recalcified human plasma and are reactive for IgG antibodies to cytomegalovirus (anti-CMV IgG). Preservative: sodium azide.

Calibrators cover the calibration range of the assay (0.0 to 250.0 AU/mL). The calibrators are at the following anti-CMV IgG concentrations:

| Calibrator | Target Anti-CMV IgG Concentration (AU/mL) |
|---|---|
| A | 0.0 |
| B | 10.0 |
| C | 50.0 |
| D | 75.0 |
| E | 125.0 |
| F | 250.0 |

The Calibrators B through F are referenced to internal reference standards at each concentration level.

Controls

The ARCHITECT CMV IgG Controls:

- Negative Control - 1 Bottle (8.0 mL): contains recalcified human plasma with protein (ovine) stabilizer. Preservative: sodium azide.
- Positive Control 1 - 1 Bottle (8.0 mL): contains recalcified human plasma and is reactive for IgG antibodies to cytomegalovirus (anti-CMV IgG). Preservative: sodium azide.

The controls are at the following proposed target anti-CMV IgG concentrations and ranges:

| **Control** | **Target Anti-CMV IgG Concentration (AU/mL)** | **Control Range (AU/mL)** |
|---|---|---|
| Negative Control (Control −) | N/A | ≤ 3.1 |
| Positive Control 1 (Control +1) | 30.0 | 15.0 to 45.0 |

The Positive Control 1 is referenced to an internal reference standard.

Principles of the Procedure

This assay is an automated, two-step immunoassay for the qualitative detection of IgG antibodies to CMV (anti-CMV IgG) in human serum and plasma using chemiluminescent microparticle immunoassay (CMIA) technology.

Pre-diluted sample, CMV virus lysate (strain AD169) coated paramagnetic microparticles, and assay diluent are combined and incubated. The anti-CMV IgG present in the sample binds to the CMV virus lysate (strain AD169) coated microparticles. The mixture is washed. Murine 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 direct relationship between the amount of anti-CMV IgG in the sample and the RLU detected by the system optics.

The presence or absence of anti-CMV IgG in the sample is determined by comparing the chemiluminescent RLU in the reaction to the cutoff RLU determined from an active calibration.

## V. Intended Use of the Device

The ARCHITECT CMV IgG assay is a chemiluminescent microparticle immunoassay (CMIA) used for the qualitative detection of IgG antibodies to cytomegalovirus in human serum, serum separator, and plasma tubes (lithium heparin, lithium heparin separator, and tripotassium EDTA) on the ARCHITECT i System.

The ARCHITECT CMV IgG assay is to be used as an aid in the diagnosis of infection with cytomegalovirus and as an aid in the determination of serological status to cytomegalovirus in individuals including women of child-bearing age.

The ARCHITECT CMV IgG assay has not been cleared for use in screening blood, plasma, or tissue donors.

## VI. Comparison of Technological Characteristics

The ARCHITECT CMV IgG assay (subject device) utilizes a CMIA methodology for the qualitative *in vitro* detection of IgG antibodies to cytomegalovirus and is intended for use on the ARCHITECT i System.

The similarities and differences between the subject device and the predicate assay are presented in the Table below.

| Similarities and Differences Between | | |
|---|---|---|
| **Device & Predicate Device(s):** | | |
| | **Device: ARCHITECT CMV IgG** | **Predicate Device: ADVIA Centaur CMV IgG Assay (k181213)** |
| **General Device Characteristic Similarities** | | |
| **Intended Use** | The ARCHITECT CMV IgG assay is a chemiluminescent microparticle immunoassay (CMIA) used for the qualitative detection of IgG antibodies to cytomegalovirus in human serum, serum separator, and plasma tubes (lithium heparin, lithium heparin separator, and tripotassium EDTA) on the ARCHITECT i System.<br>The ARCHITECT CMV IgG assay is to be used as an aid in the diagnosis of infection with cytomegalovirus and as an aid in the determination of serological status to cytomegalovirus in individuals including women of child-bearing age.<br>The ARCHITECT CMV IgG assay has not been cleared for use in screening blood, plasma, or tissue donors. | The ADVIA Centaur CMV IgG (CMV IgG) assay is for *in vitro* diagnostic use in the qualitative detection of IgG antibodies to cytomegalovirus (CMV) in human pediatric and adult serum and plasma (dipotassium EDTA, lithium heparin) using the ADVIA Centaur CP system. This assay is used to determine CMV IgG serological status and as an aid in the diagnosis of CMV infection in individuals for whom a CMV IgG test was ordered, including pregnant women.<br>The ADVIA Centaur CMV IgG assay is not intended for blood and tissue donor screening. |
| **Controls** | 2 (Negative and Positive) | 2 (Negative and Positive) |
| **Methodology** | Chemiluminescent microparticle immunoassay | Chemiluminometric Technology |
| **Type of Specimen** | Serum and Plasma | Serum and Plasma |

| General Device Characteristic Differences | | |
|---|---|---|
| **Antigen Used** | CMV Virus lysate (strain AD169) | Heterogeneous mixture of CMV viral lysate antigens |
| **Interpretation of Results** | Nonreactive: < 6.0 AU/mL<br>Grayzone/Equivocal: 6.0 to <15.0 AU/mL<br>Reactive: ≥ 15.0 AU/mL | Negative: < 1.00 Index<br>Reactive: ≥ 1.00 Index |
| **Components** | Microparticles – CMV virus lysate (strain AD169) coated microparticles in TRIS buffered saline with protein (bovine). Minimum concentration: 0.08% solids. Preservatives: ProClin 300 and antimicrobial agents.<br>Conjugate – Murine anti-human IgG acridinium-labeled conjugate in MES buffer with protein (bovine). Minimum concentration: 44 ng/mL. Preservatives: sodium azide and antimicrobial agents.<br>Assay Diluent – Calf serum and MES buffer with protein (bovine). Preservatives: ProClin 300 and ProClin 950. | Solid Phase Reagent – Streptavidin-coated paramagnetic microparticles preformed with biotinylated CMV viral lysate antigens (~0.5 mg/mL) in buffer with surfactants, sodium caseinate, and sodium azide (< 0.1%)<br>Lite Reagent - Mouse monoclonal anti-human IgG antibody labeled with acridinium ester (~0.06 µg/mL) in buffer with surfactant, bovine serum albumin (BSA), and sodium azide (< 0.1%)<br>Diluent – Potassium thiocyanate (~0.55 M), surfactant, sodium caseinate, BSA, and preservatives |
| **Calibrators** | 6 Calibrators | 2 Calibrators |
| **Calibration Storage** | Maximum of 30 days | 14 days |

## VII. Summary of Nonclinical Performance

### A. Within- Laboratory Precision (20-Day)

A study was performed based on guidance from CLSI EP05-A3.* Testing was conducted using 3 lots of the ARCHITECT CMV IgG reagents, 3 lots of the ARCHITECT CMV IgG Calibrators, 3 lots of the ARCHITECT CMV IgG Controls, and 1 instrument. Two controls and 6 recalcified human plasma panels (representing serum matrix) 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 are paired. The performance from a representative combination is shown in the following table.

| | | | Within-Run (Repeatability) | | Within-Laboratory[a] | |
|---|---|---|---|---|---|---|
| **Sample** | **N** | **Mean (AU/mL)** | **SD** | **%CV** | **SD (Range[b])** | **%CV (Range[b])** |
| Negative Control | 118 | 0.1 | 0.04 | NA[c] | 0.04 (0.00-0.04) | NA[c] |
| Positive Control 1 | 118 | 27.2 | 0.75 | 2.8 | 0.81 (0.71-0.89) | 3.0 (2.6-3.0) |
| Panel 1 | 117 | 0.4 | 0.05 | NA[c] | 0.05 (0.04-0.05) | NA[c] |
| Panel 2 | 118 | 3.3 | 0.13 | NA[c] | 0.14 (0.13-0.15) | NA[c] |
| Panel 3 | 120 | 6.8 | 0.24 | NA[c] | 0.25 (0.23-0.25) | NA[c] |
| Panel 4 | 119 | 17.6 | 0.47 | 2.7 | 0.52 (0.50-0.54) | 2.9 (2.8-2.9) |
| Panel 5 | 120 | 37.3 | 0.79 | 2.1 | 0.96 (0.96-1.06) | 2.6 (2.6-2.8) |
| Panel 6 | 118 | 200.9 | 4.14 | 2.1 | 4.86 (4.05-5.00) | 2.4 (2.2-2.5) |

[a] Includes within-run (repeatability), between-run, and between-day variability.
[b] Minimum and maximum SD or %CV across all reagent lot/calibrator lot combinations.
[c] Not applicable

* Clinical and Laboratory Standards Institute (CLSI). *Evaluation of Precision of Quantitative Measurement Procedures: Approved Guideline–Third Edition*. CLSI Document EP05-A3. Wayne, PA: CLSI; 2014.

## B. Analytical Specificity

Potentially Interfering Endogenous Substances

A study was performed based on guidance from CLSI EP07, 3rd ed.[*] and CLSI EP37, 1st ed.[†] Each substance was tested at 3 levels of the analyte (approximately 4.0 AU/mL, 12.0 AU/mL, and 20.0 AU/mL).

**No significant interference (interference ≤ +0.6 AU/mL for samples < 6.0 AU/mL, ≤ +1.5 AU/mL for samples between 6.0 AU/mL and < 15.0 AU/mL, and ≥ -10% for samples ≥ 15.0 AU/mL)** was observed at the following concentrations.

| No Significant Interference | |
|---|---|
| **Potentially Interfering Substance** | **Interferent Level** |
| Unconjugated Bilirubin | 40 mg/dL |
| Conjugated Bilirubin | 40 mg/dL |
| Hemoglobin | 1000 mg/dL |
| Total Protein | 15 g/dL |
| Triglycerides | 1650 mg/dL |

**Interference greater than +0.6 AU/mL for samples < 6.0 AU/mL** was observed at the concentration shown below for the following substance.

| Potentially Interfering Substance | Interferent Level | Analyte Level | Interference (95% CI) |
|---|---|---|---|
| Triglycerides | 2475 mg/dL | 4.0 AU/mL | 0.7 AU/mL (0.6 AU/mL, 0.8 AU/mL) |

[*] Clinical and Laboratory Standards Institute (CLSI). *Interference Testing in Clinical Chemistry*. 3rd ed. CLSI Guideline EP07. Wayne, PA: CLSI; 2018.

[†] Clinical and Laboratory Standards Institute (CLSI). *Supplemental Tables for Interference Testing in Clinical Chemistry*. 1st ed. CLSI supplement EP37. Wayne, PA: CLSI; 2018.

Potentially Interfering Drugs and Other Substances

A study was performed based on guidance from CLSI EP07, 3rd ed.[*] and CLSI EP37, 1st ed. [†] Each substance was tested at 3 levels of the analyte (approximately 4.0 AU/mL, 12.0 AU/mL, and 20.0 AU/mL).

**No significant interference (interference ≤ +0.6 AU/mL for samples < 6.0 AU/mL, ≤ +1.5 AU/mL for samples between 6.0 AU/mL and < 15.0 AU/mL, and ≥ -10% for samples ≥ 15.0 AU/mL)** was observed at the following concentrations.

| **No Significant Interference** | |
|---|---|
| **Potentially Interfering Substance** | **Interferent Level** |
| Acetaminophen | 250 mg/L |
| Ascorbic Acid | 300 mg/L |
| Beta Carotene | 6 mg/L |
| Biotin | 3510 ng/mL |
| Cidofovir | 240 mg/L |
| Diphenhydramine | 77.4 µg/dL |
| Folic Acid | 100 nmol/L |
| Foscarnet | 4320 mg/L |
| Gangciclovir | 800 mg/L |
| Ibuprofen | 500 mg/L |
| Valganciclovir | 900 mg/L |

[*] Clinical and Laboratory Standards Institute (CLSI). *Interference Testing in Clinical Chemistry*. 3rd ed. CLSI Guideline EP07. Wayne, PA: CLSI; 2018.

[†] Clinical and Laboratory Standards Institute (CLSI). *Supplemental Tables for Interference Testing in Clinical Chemistry*. 1st ed. CLSI supplement EP37. Wayne, PA: CLSI; 2018.

Potentially Interfering Other Conditions

A total of 187 specimens from individuals with medical conditions unrelated to cytomegalovirus infection and specimens containing potentially interfering substances were evaluated. One specimen tested resulted in a reactive result.

| Category | N | Number of ARCHITECT CMV IgG Reactive Results |
|---|---|---|
| Anti-dsDNA Antibodies | 10 | 0 |
| Anti-nuclear Antibody (ANA) | 8 | 0 |
| Epstein-Barr Virus (EBV) IgG | 10 | 0 |
| Hepatitis A | 9 | 0 |
| Hepatitis B | 10 | 0 |
| Hepatitis C | 10 | 0 |
| Herpes Simplex Virus Types 1 (IgG) | 10 | 0 |
| Herpes Simplex Virus Types 2 (IgG) | 6 | 0 |
| High titer CMV IgM | 1 | 0 |
| HAMA | 10 | 0 |
| Human Herpesvirus 6 (HHV6) | 10 | 0 |
| Human Immunodeficiency Virus (HIV) | 6 | 0 |
| Hyper IgG | 7 | 0 |
| Influenza vaccine recipient | 10 | 0 |
| Measles (IgG) | 10 | 0 |
| Parvovirus B19 (IgG) | 10 | 0[a] |
| Rheumatoid Factor | 10 | 0 |
| Rubella (IgG) | 10 | 0 |
| Syphilis | 10 | 0 |
| Toxoplasmosis (IgG) | 10 | 1[b] |
| Varicella Zoster Virus | 10 | 0 |
| Total | 187 | 1 |

[a] One parvovirus B19 (IgG) specimen was equivocal with the ARCHITECT CMV IgG assay and positive with the comparator assay.

[b] One toxoplasmosis (IgG) specimen was reactive with the ARCHITECT CMV IgG assay and positive with the comparator assay.

### C. CDC Panel Agreement

One CDC CMV IgG human serum panel, comprised of 80 samples that are either CMV IgG negative or CMV IgG positive, was obtained from the Centers for Disease Control and Prevention (CDC) and tested using the ARCHITECT CMV IgG assay. The results were submitted to the CDC. The CDC added their result interpretation for each sample.

The percent (%) agreement values of the ARCHITECT CMV IgG assay relative to the CDC results were calculated. The positive % agreement and corresponding two-sided 95% CI was 100% (91.59%, 100%). The negative % agreement and corresponding two-sided 95% CI was 92.11% (78.62%, 98.34%). The overall % agreement and corresponding two-sided 95% CI was 96.25% (89.43%, 99.22%).

The results are presented as a means to convey further information on the performance of this assay with a masked, characterized serum panel. This does not imply endorsement of the assay by the CDC.

## VIII. Summary of Clinical Performance

### A. Expected Values

Representative performance data are provided in this section. Results obtained in individual laboratories may vary.

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

Of the 989 specimens included in the ARCHITECT CMV IgG clinical study, 791 were from the intended use population in the US. Of the 791 specimens, 591 (74.7%) were routine order (325 female and 266 male, 0 to 91 years old) and 200 (25.3%) were pregnant females (19 to 45 years old). The mean age across the 791 subjects was 40 years.

The ARCHITECT CMV IgG assay was reactive in 508 (64.2%) of the collected specimens in the intended use population in the US (n = 791). Testing of the specimens was performed at 3 clinical testing sites located in Indianapolis Indiana, Lewisville Texas, and Palo Alto California.

The distribution of ARCHITECT CMV IgG reactive, grayzone/equivocal, and nonreactive results by age and sex is summarized in the following table.

| Age Range (Years) | Sex | ARCHITECT CMV IgG Result | | | Total |
|---|---|---|---|---|---|
| | | Number of Reactive (%) | Number of Grayzone/Equivocal (%) | Number of Nonreactive (%) | |
| 0 to 12 | Female | 4 (33.3%) | 1 (8.3%) | 7 (58.3%) | 12 |
| | Male | 7 (38.9%) | 0 (0.0%) | 11 (61.1%) | 18 |
| 13 to 21 | Female | 16 (47.1%) | 0 (0.0%) | 18 (52.9%) | 34 |
| | Male | 12 (60.0%) | 1 (5.0%) | 7 (35.0%) | 20 |
| 22 to 29 | Female | 90 (65.2%) | 0 (0.0%) | 48 (34.8%) | 138 |
| | Male | 17 (63.0%) | 0 (0.0%) | 10 (37.0%) | 27 |
| 30 to 39 | Female | 85 (50.0%) | 3 (1.8%) | 82 (48.2%) | 170 |
| | Male | 21 (56.8%) | 0 (0.0%) | 16 (43.2%) | 37 |
| 40 to 49 | Female | 38 (82.6%) | 0 (0.0%) | 8 (17.4%) | 46 |
| | Male | 25 (59.5%) | 2 (4.8%) | 15 (35.7%) | 42 |
| 50 to 59 | Female | 44 (81.5%) | 1 (1.9%) | 9 (16.7%) | 54 |
| | Male | 29 (72.5%) | 1 (2.5%) | 10 (25.0%) | 40 |
| 60 to 64 | Female | 16 (88.9%) | 0 (0.0%) | 2 (11.1%) | 18 |
| | Male | 24 (80.0%) | 0 (0.0%) | 6 (20.0%) | 30 |
| 65 to 100 | Female | 40 (75.5%) | 1 (1.9%) | 12 (22.6%) | 53 |
| | Male | 40 (76.9%) | 0 (0.0%) | 12 (23.1%) | 52 |
| Total | | 508 (64.2%) | 10 (1.3%) | 273 (34.5%) | 791 |

The ARCHITECT CMV IgG results for each category in the intended use population are summarized in the following table.

| Specimen Category | ARCHITECT CMV IgG Result | | | Total |
|---|---|---|---|---|
| | Number of Reactive (%) | Number of Grayzone/Equivocal (%) | Number of Nonreactive (%) | |
| Routine Order | 412 (69.7%) | 8 (1.4%) | 171 (28.9%) | 591 |
| Pregnant Females | 96 (48.0%) | 2 (1.0%) | 102 (51.0%) | 200 |
| Total | 508 (64.2%) | 10 (1.3%) | 273 (34.5%) | 791 |

## B. System Reproducibility

A study was performed based on guidance from CLSI EP05-A3.* Testing was conducted at each of 3 testing sites using 3 lots of the ARCHITECT CMV IgG reagents, 2 lots of the ARCHITECT CMV IgG Calibrators, 1 lot of the ARCHITECT CMV IgG Controls, and 1 instrument. Two controls and 6 recalcified human plasma panels (representing serum matrix) were tested in a minimum of 3 replicates at 2 separate times per day on 5 different days.

| Sample | N | Mean (AU/mL) | Repeatability | | Within-Laboratory[a] | | Reproducibility[b] | |
|---|---|---|---|---|---|---|---|---|
| | | | SD | %CV | SD | %CV | SD | %CV |
| Negative Control | 359 | 0.0 | 0.02 | NA[c] | 0.03 | NA [c] | 0.05 | NA[c] |
| Positive Control 1 | 360 | 27.3 | 0.80 | 2.9 | 1.00 | 3.7 | 1.24 | 4.5 |
| Panel 1 | 360 | 0.3 | 0.04 | NA[c] | 0.05 | NA [c] | 0.12 | NA[c] |
| Panel 2 | 360 | 3.1 | 0.13 | NA[c] | 0.16 | NA[c] | 0.30 | NA[c] |
| Panel 3 | 360 | 6.5 | 0.23 | NA[c] | 0.27 | NA[c] | 0.49 | NA[c] |
| Panel 4 | 359 | 17.2 | 0.58 | 3.4 | 0.69 | 4.0 | 0.84 | 4.8 |
| Panel 5 | 360 | 36.7 | 1.11 | 3.0 | 1.40 | 3.8 | 1.55 | 4.2 |
| Panel 6 | 360 | 188.9 | 4.15 | 2.2 | 5.62 | 3.0 | 7.45 | 3.9 |

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

[b] Includes repeatability, between-run, between-day, between-site, between-lot, and the site-lot interaction variability.

[c] Not applicable

* Clinical and Laboratory Standards Institute (CLSI). *Evaluation of Precision of Quantitative Measurement Procedures: Approved Guideline–Third Edition*. CLSI Document EP05-A3. Wayne, PA: CLSI; 2014.

## C. Percent Agreement

A clinical study (method comparison) was performed in the US based on guidance from CLSI EP12-A2* to evaluate the percent agreement between the ARCHITECT CMV IgG investigational assay and a current, FDA-cleared, commercially available anti-CMV IgG assay with routine order specimens collected in the US (n = 591) and outside of the US ( n= 198) and specimens collected from pregnant females in the US (n = 200).

Further evaluation of 4 specimens (3 from routine order and 1 from pregnant females) with an equivocal/grayzone result by comparator assay was performed with 2 additional current, FDA-cleared, commercially available anti-CMV IgG assays.

Comparator Result

The percent agreement between ARCHITECT CMV IgG and the comparator assay was evaluated.

| Specimen Category | ARCHITECT CMV IgG Result | Comparator Result | | | Positive % Agreement (95% CI)[a] | Negative % Agreement (95% CI)[a] |
|---|---|---|---|---|---|---|
| | | Positive | Equivocal | Negative | | |
| Routine Order | Reactive | 514 | 0 | 0 | 97.7 (514/526) (96.1, 98.7) | 99.2 (261/263) (97.3, 99.8) |
| | Equivocal | 7 | 0 | 2 | | |
| | Nonreactive | 2 | 3[c] | 261 | | |
| Pregnant Females | Reactive | 98[b] | 0 | 0 | 99.0 (98/99) (94.5, 99.8) | 100.0 (102/102) (96.4, 100.0) |
| | Equivocal | 1 | 1[d] | 0 | | |
| | Nonreactive | 0 | 0 | 102 | | |

[a] The 95% confidence interval (CI) for negative percent agreement and positive percent agreement were estimated using the Wilson Score method.

[b] Two routine order specimens were from pregnant females and therefore, were also included in the pregnant female category.

[c] Of the 3 specimens that were nonreactive by ARCHITECT CMV IgG and equivocal/grayzone by comparator assay, 2 were negative and 1 was equivocal/grayzone by consensus testing. One specimen that was concordant equivocal/grayzone by ARCHITECT CMV IgG and comparator assay was negative by consensus testing.

[d] One specimen from pregnant females that was concordant grayzone/equivocal by ARCHITECT CMV IgG and comparator assay was negative based on the consensus result from the comparator assay and 2 additional current, FDA-cleared, commercially available anti-CMV IgG assays.

* Clinical and Laboratory Standards Institute (CLSI). *User Protocol for Evaluation of Qualitative Test Performance; Approved Guideline—Second Edition*. CLSI Document EP12-A2. Wayne, PA: CLSI; 2008.

## IX. Conclusion Drawn from Nonclinical and Clinical Laboratory Studies

The results presented in this 510(k) premarket notification demonstrate that the subject device (ARCHITECT CMV IgG) performance is substantially equivalent to the predicate assay (VIDAS CMV IgG assay, k920661).