Biokit S.A.
Dominique Monferrer
Regulatory Affairs Director
Av. Can Montcau 7
Lliçà d'Amunt, 08186
Spain

August 07, 2024

Re: K233606
Trade/Device Name: ADVIA Centaur EBV-VCA IgM
Regulation Number: 21 CFR 866.3235
Regulation Name: Epstein-Barr Virus Serological Reagents
Regulatory Class: Class I, reserved
Product Code: LSE
Dated: July 29, 2024
Received: July 29, 2024

Dear Dominique Monferrer:

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.

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,

Bhawna Poonia -S

for

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: 07/31/2026
*See PRA Statement below.*

Submission Number *(if known)*

K233606

Device Name

ADVIA Centaur EBV-VCA IgM (10720837)

Indications for Use *(Describe)*

The ADVIA Centaur EBV-VCA IgM (EBVM) assay is for in vitro diagnostic use in the qualitative detection of IgM antibodies to the viral capsid antigen (VCA) of the Epstein-Barr virus (EBV) in human pediatric (2-21 years old) and adult serum and plasma (EDTA and lithium heparin) using the ADVIA Centaur XP system. When used in conjunction with other EBV markers, this assay is intended for use as an aid in the diagnosis of Epstein-Barr virus infection, such as infectious mononucleosis.

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.**

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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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.<br>Av. Can Montcau, 7<br>Lliçà d'Amunt 08186<br>Barcelona (Spain) |

| | |
|---|---|
| **2. Contact Person** | Dominique Monferrer, Regulatory Affairs Director<br>Phone: +34 93 860 90 00<br>Email: dmonferrer@werfen.com |

| | |
|---|---|
| **3. Preparation Date** | 2023-Nov-09 |

| | |
|---|---|
| **4. Device Trade Name** | ADVIA Centaur EBV-VCA IgM |

| | | |
|---|---|---|
| **5. Regulatory Information** | Regulation Number | 21 CFR 866.3235 |
| | Regulation Description | Epstein–Barr Virus serological reagents |
| | Classification | Class I (general controls) |
| | Product Code | LSE |
| | Classification Panel | Microbiology |

| | |
|---|---|
| **6. Predicate Device** | k040120 (LIAISON EBV IgM) |

| | |
|---|---|
| **7. Indications for Use / Intended Use** | The ADVIA Centaur EBV-VCA IgM (EBVM) assay is for *in vitro* diagnostic use in the qualitative detection of IgM antibodies to the viral capsid antigen (VCA) of the Epstein-Barr virus (EBV) in human pediatric (2-21 years old) and adult serum and plasma (EDTA and lithium heparin) using the ADVIA Centaur XP system. When used in conjunction with other EBV markers, this assay is intended for use as an aid in the diagnosis of Epstein-Barr virus infection, such as infectious mononucleosis. |

| | |
|---|---|
| **8. Principles of the procedure** | The ADVIA Centaur EBV-VCA IgM assay is a fully automated 2-step sandwich immunoassay using acridinium ester chemiluminescent technology. The specimen is incubated with the Ancillary Well Reagent and the Solid Phase, which contains an EBV-VCA IgM specific antigen. Antigen-antibody complexes will form if anti EBV-VCA IgM antibody is present in the specimen. The Lite Reagent contains monoclonal anti-human IgM labeled with acridinium ester and is used to detect EBV-VCA IgM in the specimen. |

| COMPARISON PREDICATE | | |
|---|---|---|
| **Item** | **Predicate** | **New Device** |
| **Trade Names** | LIAISON EBV IgM | ADVIA Centaur EBV-VCA IgM |
| **510K no.** | k040120 | K233606 |
| **Manufacturer** | DiaSorin, S.p.A.<br>Via Crescentino, snc<br>13040 Saluggia (Vercelli) Italy | Siemens Healthcare Diagnostics Inc.<br>511 Benedict Avenue,<br>Tarrytown, NY 10591 USA |
| **Intended use** | The LIAISON EBV IgM assay uses chemiluminescent immunoassay (CLIA) technology on the LIAISON Analyzer family* for the qualitative determination of specific IgM antibodies to Epstein-Barr virus (EBV) viral capsid antigen (VCA) p18 synthetic peptide in human serum. When performed in conjunction with other EBV markers, this assay can be used as an aid in the clinical laboratory diagnosis of Epstein-Barr Viral Syndrome in patients with signs and symptoms of EBV infection such as infectious mononucleosis.<br>*(LIAISON and LIAISON XL) | The ADVIA Centaur EBV-VCA IgM (EBVM) assay is for *in vitro* diagnostic use in the qualitative detection of IgM antibodies to the viral capsid antigen (VCA) of the Epstein-Barr virus (EBV) in human pediatric (2-21 years old) and adult serum and plasma (EDTA and lithium heparin) using the ADVIA Centaur XP system. When used in conjunction with other EBV markers, this assay is intended for use as an aid in the diagnosis of Epstein-Barr virus infection, such as infectious mononucleosis. |
| ***Similarities*** | | |
| **Measurand** | Epstein Barr Virus IgM to Viral Capsid Antigen | To detect IgM antibodies to the viral capsid antigen (VCA) of Epstein Barr virus (EBV). |
| **Regulation Section** | 21 CFR 866.3235 | Same |

| | | |
|---|---|---|
| **Product Code** | LLM, LSE | LSE |
| **Classification** | Class I (general controls) | Same |
| **Assay Type** | Qualitative | Same |
| **Technology** | Chemiluminescent immunoassay (CLIA) | Same |
| **Antigen** | p18 | Same |
| ***Differences*** | | |
| **Sample type** | Human serum | Human serum and plasma (EDTA and lithium heparin) |
| **Target Population** | Adults | Pediatric and adult |

## 9. Performance Summary

Clinical Study

A multisite clinical study to compare the reference method with ADVIA Centaur EBV-VCA IgM was performed.

**Comparison of Results: Total Study Population**

A total of 1428 leftover samples were collected over a contiguous time period from individuals for whom an EBV test was ordered (population 1). Of these, 188 were from unclassified serostatus individuals. Two hundred and two (202) samples with a known EBV VCA IgM positive result (population 2) were evaluated as well. Of these, 4 were from unclassified serostatus individuals. The study results otherwise showed that these populations included individuals with acute infection, past infection, or no serologic evidence of EBV infection.

Samples were tested using the ADVIA Centaur EBVM assay and an FDA-cleared EBV VCA IgM reference assay. Equivocal reference assay results were resolved by 2 other comparative assays. The results obtained are presented in the following tables:

| Population 1 | | | | |
|---|---|---|---|---|
| **ADVIA Centaur EBVM Assay** | **Reference Assay** | | | |
| | **Negative** | **Equivocal** | **Positive** | **Total** |
| Nonreactive | 1294 | 2 | 26 | 1322 |
| Reactive | 41 | 3 | 62 | 106 |
| **Total** | **1335** | **5** | **88** | **1428** |
| | **NPA**[a]=96.7% (1294/1338) 95% CI[b]: 95.6% - 97.5% | | **PPA**[c]=68.9% (62/90) 95% CI: 58.7% - 77.5% | |

[a] Negative percent agreement.
[b] Confidence interval.
[c] Positive percent agreement.

Out of 90 samples that were positive on the reference assay, 53 were primary acute, and of those, 48 samples were positive on the ADVIA Centaur EBVM assay.

% Positive Agreement for primary acute patients = 90.6 % (48 / 53)
95% Confidence Interval = 79.7 % - 95.9 %

In this study, primary acute infection was defined by the presence of either EBV IgM or heterophile antibodies, and the absence of EBNA IgG.

| Population 2 | | | | |
|---|---|---|---|---|
| **ADVIA Centaur EBM Assay** | **Reference Assay** | | | |
| | **Negative** | **Equivocal** | **Positive** | **Total** |
| Nonreactive | 0 | 0 | 0 | 0 |
| Reactive | 0 | 0 | 202 | 202 |
| **Total** | **0** | **0** | **202** | **202** |
| | N/A[a] | | **PPA**[b]=100% (202/202) 95% CI[c]: 98.1% - 100% | |

[a] Not applicable.
[b] Positive percent agreement.
[c] Confidence interval.

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**Percent of Agreement: Pediatric Population**

The agreement between the ADVIA Centaur EBVM assay and the reference EBV VCA IgM assay in the pediatric subjects from Population 1 and 2 is presented in the tables below.

Population 1 included samples from subjects with signs and symptoms for whom an EBV antibody test was ordered. Of these, 84 were from unclassified serostatus individuals. The study results otherwise showed that this population included individuals with acute, past, or no serologic evidence of EBV infection. Population 2 included samples with a known EBV VCA IgM positive result to supplement numbers for positive EBV VCA IgM. Of these, 3 were from unclassified serostatus individuals.

| **Population 1** | | | | |
|---|---|---|---|---|
| **ADVIA Centaur EBVM Assay** | **Reference Assay** | | | |
| | **Negative** | **Equivocal** | **Positive** | **Total** |
| Nonreactive | 402 | 0 | 9 | 411 |
| Reactive | 19 | 1 | 48 | 68 |
| **Total** | **421** | **1** | **57** | **479** |
| | **NPA**[a]=95.3% (402/422) 95% CI[b]: 92.8% - 96.9% | | **PPA**[c]=84.2% (48/57) 95% CI: 72.6% - 91.5% | |

[a] Negative percent agreement.
[b] Confidence interval.
[c] Positive percent agreement.

Out of 57 pediatric subject samples that were positive on the reference assay, 46 were primary acute, and of those, 42 samples were positive on the ADVIA Centaur EBVM assay.

% Positive Agreement for primary acute patients = 91.3 % (42 / 46)
95% Confidence Interval = 79.7 % - 96.6 %

In this study, primary acute infection was defined by the presence of either EBV IgM or heterophile antibodies, and the absence of EBNA IgG.

| Population 2 | | | | |
|---|---|---|---|---|
| **ADVIA Centaur EBVM Assay** | **Reference Assay** | | | |
| | **Negative** | **Equivocal** | **Positive** | **Total** |
| Nonreactive | 0 | 0 | 0 | 0 |
| Reactive | 0 | 0 | 155 | 155 |
| **Total** | **0** | **0** | **155** | **155** |
| | N/A[a] | | **PPA**[b]=100% (155/155)<br>95% CI[c]: 97.6% - 100% | |

[a] Not applicable.
[b] Positive percent agreement.
[c] Confidence interval.

Precision

Precision was determined in accordance with CLSI EP05-A3 using the Negative and Positive Controls as well as 5 serum samples and 5 EDTA plasma samples prepared at different levels across the assay range. Samples (N=240) were assayed in replicates of 2 with 2 runs per day using three reagent lots in a 20-day protocol.

The following results are representative of the performance of the assay:

| **Sample** | **Mean Value (Index)** | **Repeatability** | | **Between Run** | | **Between Day** | | **Between Lot** | | **Total Precision** | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | | **SD[b] (Index)** | **CV[c] (%)** | **SD (Index)** | **CV (%)** | **SD (Index)** | **CV (%)** | **SD (Index)** | **CV (%)** | **SD (Index)** | **CV (%)** |
| Serum A | 0.75 | 0.019 | 2.5 | 0.018 | 2.4 | 0.017 | 2.3 | 0.081 | 10.9 | 0.087 | 11.6 |
| Serum B | 0.96 | 0.024 | 2.5 | 0.023 | 2.4 | 0.023 | 2.4 | 0.076 | 8.0 | 0.086 | 9.0 |
| Serum C | 1.39 | 0.034 | 2.4 | 0.030 | 2.2 | 0.041 | 2.9 | 0.119 | 8.5 | 0.133 | 9.6 |
| Serum D | 3.16 | 0.075 | 2.4 | 0.053 | 1.7 | 0.101 | 3.2 | 0.173 | 5.5 | 0.221 | 7.0 |
| Serum E | 7.22 | 0.217 | 3.0 | 0.140 | 1.9 | 0.269 | 3.7 | 0.531 | 7.4 | 0.649 | 9.0 |
| Plasma, EDTA A | 0.74 | 0.019 | 2.6 | 0.026 | 3.4 | 0.023 | 3.0 | 0.048 | 6.4 | 0.062 | 8.3 |
| Plasma, EDTA B | 1.00 | 0.022 | 2.2 | 0.031 | 3.1 | 0.027 | 2.7 | 0.061 | 6.1 | 0.077 | 7.7 |

| Sample | Mean Value (Index) | Repeatability | | Between Run | | Between Day | | Between Lot | | Total Precision | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | | SD[b] (Index) | CV[c] (%) | SD (Index) | CV (%) | SD (Index) | CV (%) | SD (Index) | CV (%) | SD (Index) | CV (%) |
| Plasma, EDTA C | 1.40 | 0.029 | 2.1 | 0.045 | 3.2 | 0.041 | 2.9 | 0.118 | 8.4 | 0.136 | 9.7 |
| Plasma, EDTA D | 3.35 | 0.081 | 2.4 | 0.062 | 1.8 | 0.111 | 3.3 | 0.308 | 9.2 | 0.342 | 10.2 |
| Plasma, EDTA E | 7.63 | 0.218 | 2.9 | 0.367 | 4.8 | 0.320 | 4.2 | 0.466 | 6.1 | 0.709 | 9.3 |
| Control 1 | 0.28 | 0.012 | N/A[c] | 0.014 | N/A | 0.010 | N/A | 0.011 | N/A | 0.024 | N/A |
| Control 2 | 3.02 | 0.071 | 2.3 | 0.049 | 1.6 | 0.088 | 2.9 | 0.214 | 7.1 | 0.247 | 8.2 |

[a] Standard deviation.
[b] Coefficient of variation.
[c] Not applicable.

Reproducibility

Reproducibility was determined in accordance with CLSI EP05-A3. Testing was performed using 3 external sites and 1 reagent lot. A 4-member serum panel and a 4-member plasma EDTA panel were assayed in replicates of 3 with 2 runs per day, over 5 days (N = 90 for each sample).

| Sample | N[a] | Mean (Index) | Within-Run Repeatability | | Between-Runs | | Between-Days | | Between-Sites | | Reproducibility | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | SD[b] | CV[c] (%) | SD | CV (%) | SD | CV (%) | SD | CV (%) | SD | CV (%) |
| Serum A | 90 | 0.85 | 0.023 | 2.7 | 0.028 | 3.3 | 0.004 | 0.5 | 0.017 | 2.0 | 0.040 | 4.7 |
| Serum B | 90 | 1.00 | 0.024 | 2.4 | 0.020 | 2.1 | 0.008 | 0.8 | 0.011 | 1.1 | 0.034 | 3.5 |
| Serum C | 90 | 1.57 | 0.038 | 2.4 | 0.022 | 1.4 | 0.014 | 0.9 | 0.028 | 1.8 | 0.054 | 3.4 |
| Serum D | 90 | 3.30 | 0.099 | 3.0 | 0.025 | 0.8 | 0.009 | 0.3 | 0.081 | 2.5 | 0.131 | 4.0 |
| Plasma, EDTA A | 90 | 0.75 | 0.023 | N/A[d] | 0.026 | N/A | 0.000 | N/A | 0.013 | N/A | 0.037 | N/A |
| Plasma, EDTA B | 90 | 1.00 | 0.035 | 3.5 | 0.023 | 2.3 | 0.000 | 0.0 | 0.009 | 0.9 | 0.043 | 4.3 |
| Plasma, EDTA C | 90 | 1.49 | 0.036 | 2.4 | 0.038 | 2.5 | 0.000 | 0.0 | 0.016 | 1.1 | 0.055 | 3.7 |
| Plasma, EDTA D | 90 | 3.72 | 0.103 | 2.8 | 0.088 | 2.4 | 0.054 | 1.4 | 0.106 | 2.8 | 0.180 | 4.9 |
| Control 1 | 90 | 0.24 | 0.012 | N/A | 0.004 | N/A | 0.006 | N/A | 0.009 | N/A | 0.017 | N/A |
| Control 2 | 90 | 3.20 | 0.248 | 7.8 | 0.000 | 0.0 | 0.075 | 2.3 | 0.145 | 4.5 | 0.297 | 9.3 |

[a] Number of measurements
[b] Standard deviation
[c] Coefficient of variation
[d] Not Applicable

The assay was designed to have the following reproducibility when using a 5-day protocol in accordance with CLSI Document EP05-A3:

| Concentration Interval | Reproducibility |
|---|---|
| ≤ 0.80 Index | N/A[a] |
| > 0.80 Index | ≤ 20% CV |

[a] Not applicable.

Specimen Equivalency

The specimen equivalency study was determined with the weighted Deming regression model using the ADVIA Centaur XP in accordance with CLSI document EP09c-ed3.

This study was performed using 70 sets of matched samples of three matrixes (serum separator tube (SST), EDTA plasma and lithium heparin plasma) from commercial sources.

Samples were analyzed in one replicate in randomized order using one reagent lot.

| Tube (y) vs. Serum (x) | Regression Equation | Sample Interval | N[a] | r[b] |
|---|---|---|---|---|
| **Plasma, EDTA** | y=1.00x-0.03 Index | 0.12-12.35 Index | 70 | 1.00 |
| **Plasma, lithium heparin** | y=1.00x-0.05 Index | 0.10-11.49 Index | 70 | 1.00 |

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

The results support that EDTA Plasma and Lithium Heparin Plasma are equivalent matrixes to Serum.

Interferences

Potential interference was evaluated using the ADVIA Centaur XP system in accordance with guidance from the CLSI documents EP07-ed3 and EP-37-ed1.

Three matrixes (serum, EDTA plasma and lithium heparin plasma) have been analyzed in this study. For each sample (nonreactive, low reactive and high reactive) and each interfering substance to test, two samples (Control and Test) were analyzed.

The acceptable difference with respect to the value reported for Control sample from the compounds listed below is ±10 % bias for reactive samples and ±0.10 Index for nonreactive samples.

The following substances do not interfere with the assay in the different matrixes at the concentrations indicated below:

| Substance | Substance Test Concentration |
|---|---|
| Hemoglobin | 1000 mg/dL |
| Bilirubin, conjugated | 40 mg/dL |
| Bilirubin, unconjugated | 40 mg/dL |
| Lipemia (Intralipid) | 1500 mg/dL |
| Biotin | 3510 ng/mL |
| Cholesterol | 502 mg/dL |
| Protein (hyperproteinemic) | 15 g/dL |
| Protein (hypoproteinemic) | 3 g/dL |

Cross-reactivity

The ADVIA Centaur EBVM assay was evaluated for potential cross-reactivity with other viral antibodies and disease state specimens using the ADVIA Centaur system.

A total of 371 samples were analyzed with ADVIA Centaur EBV-VCA IgM on the ADVIA Centaur XP system and with an EBV VCA IgM comparative assay.

The data are summarized in the following table.

| Clinical Category | Number Tested | ADVIA Centaur EBV-VCA IgM Assay Results | | Comparative EBV-VCA IgM Assay Results | | |
|---|---|---|---|---|---|---|
| | | Nonreactive | Reactive | Negative | Equivocal | Positive |
| Cytomegalovirus (CMV) IgG | 10 | 10 | 0 | 10 | 0 | 0 |
| Cytomegalovirus (CMV) IgM | 10 | 7 | 3 | 7 | 0 | 3 |
| Parvovirus B19 IgM | 10 | 10 | 0 | 9 | 0 | 1 |
| *Toxoplasma gondii* IgG | 10 | 10 | 0 | 10 | 0 | 0 |
| *Toxoplasma gondii* IgM | 28 | 22 | 6 | 24 | 0 | 4 |
| Rubella IgG | 20 | 18 | 2 | 19 | 1 | 0 |
| Rubella IgM | 11 | 11 | 0 | 10 | 1 | 0 |
| Hepatitis B Virus (HBV) IgM | 11 | 11 | 0 | 11 | 0 | 0 |

| Clinical Category | Number Tested | ADVIA Centaur EBV-VCA IgM Assay Results | | Comparative EBV-VCA IgM Assay Results | | |
|---|---|---|---|---|---|---|
| | | Nonreactive | Reactive | Negative | Equivocal | Positive |
| Hepatitis A Virus (HAV) IgM | 10 | 7 | 3 | 8 | 0 | 2 |
| Hepatitis C Virus (HCV) | 11 | 11 | 0 | 10 | 0 | 1 |
| Human Immunodeficiency Virus (HIV) | 10 | 9 | 1 | 9 | 0 | 1 |
| Herpes Simplex Virus (HSV-1) IgG | 11 | 11 | 0 | 11 | 0 | 0 |
| Herpes Simplex Virus (HSV-1) IgM | 10 | 10 | 0 | 10 | 0 | 0 |
| Herpes Simplex Virus (HSV-2) IgG | 12 | 12 | 0 | 12 | 0 | 0 |
| Herpes Simplex Virus (HSV-2) IgM | 11 | 9 | 2 | 10 | 0 | 1 |
| *Treponema pallidum* (Syphilis) | 11 | 11 | 0 | 11 | 0 | 0 |
| Varicella Zoster Virus (VZV) IgM | 10 | 9 | 1 | 10 | 0 | 0 |
| Measles virus IgM | 10 | 10 | 0 | 10 | 0 | 0 |
| Mumps virus IgM | 10 | 10 | 0 | 10 | 0 | 0 |
| *Borrelia burgdorferi* IgM (Lyme IgM) | 11 | 11 | 0 | 11 | 0 | 0 |
| Influenza virus IgM | 10 | 10 | 0 | 10 | 0 | 0 |
| *Mycoplasma pneumoniae* IgM | 18 | 15 | 3 | 16 | 0 | 2 |
| Antinuclear antibodies (ANA) | 10 | 10 | 0 | 10 | 0 | 0 |
| Rheumatic Factors (RF) | 11 | 10 | 1 | 11 | 0 | 0 |
| Human Anti-mouse antibodies (HAMA) | 10 | 10 | 0 | 10 | 0 | 0 |
| Human Herpes Virus (HHV6) | 14 | 14 | 0 | 14 | 0 | 0 |
| Systemic Lupus Erythematosus (SLE) | 10 | 10 | 0 | 10 | 0 | 0 |
| Flu vaccinated patients | 10 | 10 | 0 | 10 | 0 | 0 |
| Elevated IgG | 10 | 10 | 0 | 10 | 0 | 0 |
| Elevated IgM | 11 | 11 | 0 | 11 | 0 | 0 |
| Epstein Barr Virus (EBV) Viral Capsid Antigen (VCA) IgG | 10 | 10 | 0 | 10 | 0 | 0 |
| Epstein Barr Virus (EBV) Epstein-Barr Nuclear Antigen (EBNA) IgG | 10 | 9 | 1 | 9 | 0 | 1 |
| **Total** | **371** | **348** | **23** | **353** | **2** | **16** |

## 10. Stability

The onboard stability of the ADVIA Centaur EBV-VCA IgM reagent is 28 days with a calibration interval of 28 days. The onboard stability of the ADVIA Centaur EBV-VCA IgM Calibrators is 8 hours. The opened vial stability of the ADVIA Centaur EBV-VCA IgM Calibrators is 60 days when stored at 2-8°C. Unopened reagents and calibrators are stable until the expiration date printed on the box label when stored at 2-8°C.

## 11. Conclusion

The analytical and clinical study results demonstrate that the ADVIA Centaur EBV-VCA IgM is substantially equivalent to the predicate device, LIAISON EBV IgM (FDA cleared under K040120).