



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

August 07, 2024

Re: K233605  
Trade/Device Name: ADVIA Centaur EBV-EBNA IgG  
Regulation Number: 21 CFR 866.3235  
Regulation Name: Epstein-Barr Virus Serological Reagents  
Regulatory Class: Class I, reserved  
Product Code: LLM, 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](mailto: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

## Indications for Use

Submission Number (if known)

K233605

Device Name

ADVIA Centaur EBV-EBNA IgG (10720840)

Indications for Use (Describe)

The ADVIA Centaur EBV-EBNA IgG (EBVnaG) assay is for in vitro diagnostic use in the qualitative detection of IgG antibodies to Epstein-Barr virus (EBV) nuclear antigen (EBNA) 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.**

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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.

<b>1. Submitter's Information</b>	Biokit, S.A. Av. Can Montcau, 7 Lliçà d'Amunt 08186 Barcelona (Spain)
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<b>2. Contact Person</b>	Dominique Monferrer, Regulatory Affairs Director Phone: +34 93 860 90 00 Email: dmonferrer@werfen.com
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<b>3. Preparation Date</b>	2023-Nov-09
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<b>4. Device Trade Name</b>	ADVIA Centaur EBV-EBNA IgG
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<b>5. Regulatory Information</b>	Regulation Number	21 CFR 866.3235
	Regulation Description	Epstein-Barr Virus serological reagents
	Classification	Class I (general controls)
	Product Code	LLM, LSE
	Classification Panel	Microbiology

<b>6. Predicate Device</b>	k040120 (LIAISON EBNA IgG)
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## **7. Indications for Use / Intended Use**

The ADVIA Centaur EBV-EBNA IgG (EBVnaG) assay is for *in vitro* diagnostic use in the qualitative detection of IgG antibodies to Epstein-Barr virus (EBV) nuclear antigen (EBNA) 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-EBNA IgG 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-EBNA IgG specific antigen. Antigen-antibody complexes will form if anti-EBV-EBNA IgG antibody is present in the specimen. The Lite Reagent contains monoclonal anti-human IgG labeled with acridinium ester and is used to detect EBV-EBNA IgG in the specimen.

<b>COMPARISON PREDICATE</b>		
<b>Item</b>	<b>Predicate</b>	<b>New Device</b>
<b>Trade Names</b>	LIAISON EBNA IgG	ADVIA Centaur EBV-EBNA IgG
<b>510K no.</b>	k040120	K233605
<b>Manufacturer</b>	DiaSorin, S.p.A. Via Crescentino, snc 13040 Saluggia (Vercelli) Italy	Siemens Healthcare Diagnostics Inc. 511 Benedict Avenue, Tarrytown, NY 10591 USA
<b>Intended use</b>	<p>The LIAISON EBNA IgG assay uses chemiluminescent immunoassay (CLIA) technology on the LIAISON Analyzer family* for the qualitative determination of specific IgG antibodies to Epstein-Barr virus (EBV) nuclear antigen synthetic peptide (EBNA-1) 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.</p> <p>*(LIAISON and LIAISON XL)</p>	<p>The ADVIA Centaur EBV-EBNA IgG assay is for <i>in vitro</i> diagnostic use in the qualitative detection of IgG antibodies to Epstein-Barr virus (EBV) nuclear antigen (EBNA) 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.</p>
<b>Similarities</b>		
<b>Measurand</b>	Specific IgG antibodies to Epstein-Barr virus (EBV) nuclear antigen synthetic peptide (EBNA-1).	To detect IgG antibodies to the Epstein-Barr virus (EBV) nuclear antigen (EBNA).
<b>Regulation Section</b>	21 CFR 866.3235	Same

<b>Product Code</b>	LLM, LSE	Same
<b>Classification</b>	Class I (general controls)	Same
<b>Assay Type</b>	Qualitative	Same
<b>Technology</b>	Chemiluminescent immunoassay (CLIA)	Same
<b>Antigen</b>	EBNA-1	Same
<b><i>Differences</i></b>		
<b>Sample type</b>	Human serum	Human serum and plasma (EDTA and lithium heparin)
<b>Target Population</b>	Adults	Pediatric and adult

## 9. Performance Summary

### Clinical Study

A multisite clinical study to compare the reference method with ADVIA Centaur EBV-EBNA IgG 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. One-hundred sixty-seven (167) samples with a known EBV EBNA IgG negative result (population 2) were evaluated as well. Of these, 14 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 EBVnaG assay and an FDA cleared EBV EBNA IgG 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 EBVnaG Assay	Reference Assay			
	Negative	Equivocal	Positive	Total
Nonreactive	323	2	4	329
Reactive	23	2	1074	1099
<b>Total</b>	<b>346</b>	<b>4</b>	<b>1078</b>	<b>1428</b>
	<b>NPA<sup>a</sup>=92.8%</b> (323/348) 95% CI <sup>b</sup> : 89.6% - 95.1%		<b>PPA<sup>c</sup>=99.4%</b> (1074/1080) 95% CI: 98.8% - 99.7%	

<sup>a</sup> Negative percent agreement.

<sup>b</sup> Confidence interval.

<sup>c</sup> Positive percent agreement.

Population 2				
ADVIA Centaur EBVnaG Assay	Reference Assay			
	Negative	Equivocal	Positive	Total
Nonreactive	164	0	0	164
Reactive	3	0	0	3
<b>Total</b>	<b>167</b>	<b>0</b>	<b>0</b>	<b>167</b>
	<b>NPA<sup>a</sup>=98.2%</b> (164/167) 95% CI <sup>b</sup> : 94.9% - 99.4%		N/A <sup>c</sup>	

<sup>a</sup> Negative percent agreement.

<sup>b</sup> Confidence interval.

<sup>c</sup> Not applicable.

## Percent of Agreement: Pediatric Population

The agreement between the ADVIA Centaur EBVnaG assay and the reference EBV EBNA IgG 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 unclassified serostatus individuals. The study results showed that this population included individuals with acute, past, or no serologic evidence of EBV infection. Population 2 included samples with a known EBV EBNA IgG negative result to supplement numbers for negative EBV EBNA IgG. Of these, 6 were unclassified serostatus individuals.

Population 1				
ADVIA Centaur EBVnaG Assay	Reference Assay			
	Negative	Equivocal	Positive	Total
Nonreactive	220	2	2	224
Reactive	5	1	249	255
<b>Total</b>	<b>225</b>	<b>3</b>	<b>251</b>	<b>479</b>
	<b>NPA<sup>a</sup>=97.3%</b> (220/226) 95% CI <sup>b</sup> : 94.3% - 98.8%		<b>PPA<sup>c</sup>=98.4%</b> (249/253) 95% CI: 96.0% - 99.4%	

<sup>a</sup> Negative percent agreement.

<sup>b</sup> Confidence interval.

<sup>c</sup> Positive percent agreement.

Population 2				
ADVIA Centaur EBVnaG Assay	Reference Assay			
	Negative	Equivocal	Positive	Total
Nonreactive	72	0	0	72
Reactive	0	0	0	0
<b>Total</b>	<b>72</b>	<b>0</b>	<b>0</b>	<b>72</b>
	<b>NPA<sup>a</sup>=100%</b> (72/72) 95% CI <sup>b</sup> : 94.9% - 100%		N/A <sup>c</sup>	

<sup>a</sup> Negative percent agreement.

<sup>b</sup> Confidence interval.

<sup>c</sup> Not applicable.

## 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 <sup>b</sup> (Index)	CV <sup>c</sup> (%)	SD (Index)	CV (%)	SD (Index)	CV (%)	SD (Index)	CV (%)	SD (Index)	CV (%)
Serum A	0.69	0.015	2.1	0.026	3.8	0.000	0.0	0.006	0.9	0.030	4.4
Serum B	1.01	0.019	1.8	0.029	2.8	0.000	0.0	0.092	9.0	0.098	9.7
Serum C	1.34	0.024	1.8	0.029	2.2	0.047	3.5	0.167	12.5	0.178	13.3
Serum D	4.98	0.074	1.5	0.084	1.7	0.166	3.3	0.326	6.5	0.382	7.7
Serum E	8.54	0.164	1.9	0.195	2.3	0.145	1.7	0.187	2.2	0.348	4.1
Plasma, EDTA A	0.71	0.015	2.1	0.024	3.4	0.005	0.7	0.009	1.3	0.030	4.3
Plasma, EDTA B	0.95	0.019	2.1	0.028	2.9	0.009	0.9	0.083	8.8	0.090	9.5
Plasma, EDTA C	1.33	0.025	1.9	0.047	3.6	0.021	1.6	0.000	0.0	0.058	4.3
Plasma, EDTA D	4.93	0.108	2.2	0.122	2.5	0.132	2.7	0.121	2.5	0.242	4.9
Plasma, EDTA E	8.76	0.155	1.8	0.239	2.7	0.116	1.3	0.254	2.9	0.399	4.6
Control 1	0.32	0.007	N/A <sup>c</sup>	0.007	N/A	0.009	N/A	0.006	N/A	0.014	N/A
Control 2	3.16	0.051	1.6	0.065	2.1	0.079	2.5	0.061	1.9	0.130	4.1

<sup>a</sup> Standard deviation.

<sup>b</sup> Coefficient of variation.

<sup>c</sup> Not Applicable.

## Reproducibility

Reproducibility was determined in accordance with CLSI EP05-A3. Testing was performed using 3 sites and 1 reagent lot. A 5-member serum panel and a 5-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 <sup>a</sup>	Mean (Index)	Within-Run Repeatability		Between-Runs		Between-Days		Between-Sites		Reproducibility	
			SD <sup>b</sup>	CV <sup>c</sup> (%)	SD	CV (%)	SD	CV (%)	SD	CV (%)	SD	CV (%)
Serum A	90	0.77	0.023	N/A	0.023	N/A	0.010	N/A	0.034	N/A	0.048	N/A
Serum B	90	1.07	0.066	6.1	0.051	4.7	0.000	0.0	0.065	6.0	0.105	9.8
Serum C	90	1.40	0.031	2.2	0.012	0.9	0.028	2.0	0.036	2.6	0.056	4.0
Serum D	90	4.99	0.103	2.1	0.119	2.4	0.077	1.6	0.255	5.1	0.310	6.2
Serum E	90	8.85	0.173	2.0	0.316	3.6	0.185	2.1	0.490	5.5	0.635	7.2
Plasma, EDTA A	90	0.78	0.025	N/A <sup>d</sup>	0.001	N/A	0.017	N/A	0.032	N/A	0.044	N/A
Plasma, EDTA B	90	1.06	0.024	2.3	0.016	1.5	0.025	2.3	0.037	3.5	0.053	5.0
Plasma, EDTA C	90	1.39	0.032	2.3	0.014	1.0	0.022	1.6	0.068	4.9	0.080	5.7
Plasma, EDTA D	90	5.06	0.104	2.1	0.061	1.2	0.103	2.0	0.258	5.1	0.303	6.0
Plasma, EDTA E	90	8.75	0.824	9.4	0.093	1.1	0.148	1.7	0.404	4.6	0.934	10.7
Control 1	90	0.36	0.010	N/A	0.009	N/A	0.000	N/A	0.017	N/A	0.022	N/A
Control 2	90	3.31	0.057	1.7	0.043	1.3	0.000	0.0	0.113	3.4	0.134	4.0

<sup>a</sup> Number of measurements

<sup>b</sup> Standard deviation

<sup>c</sup> Coefficient of variation

<sup>d</sup> 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 <sup>a</sup>
> 0.80 Index	≤ 20.0% CV

<sup>a</sup> 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 between 97-98 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.

<b>Specimen Type</b>	<b>Regression Equation</b>	<b>Sample Interval</b>	<b>N<sup>a</sup></b>	<b>r<sup>b</sup></b>
<b>Plasma, EDTA</b>	$y = 1.00x - 0.01$ Index	0.03-19.86 Index	98	1.00
<b>Plasma, lithium heparin</b>	$y = 0.98x - 0.01$ Index	0.03-17.87 Index	97	0.99

<sup>a</sup> Number of samples tested.

<sup>b</sup> 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 respect to the value reported for Control sample from the compounds listed below is  $\pm 10\%$  bias for reactive samples and  $\pm 0.10$  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 EBVnaG assay was evaluated for potential cross-reactivity with viral antibodies and disease state specimens using the ADVIA Centaur system.

A total of 330 samples were analyzed with ADVIA Centaur EBV-EBNA IgG on the ADVIA Centaur XP system and with an EBV EBNA IgG comparative assay.

The data are summarized in the following table:

Clinical Category	Number Tested	ADVIA Centaur EBV-EBNA IgG Assay Results		Comparative EBV-EBNA IgG Assay Results		
		Nonreactive	Reactive	Negative	Equivocal	Positive
Cytomegalovirus (CMV) IgG	10	5	5	5	0	5
Cytomegalovirus (CMV) IgM	10	9	1	9	0	1
Parvovirus B19 IgG	10	5	5	5	0	5
<i>Toxoplasma gondii</i> IgG	10	5	5	5	0	5
<i>Toxoplasma gondii</i> IgM	10	5	5	5	0	5
Rubella IgG	18	7	11	7	0	11
Rubella IgM	11	3	8	3	0	8
Hepatitis B Virus (HBV) IgG	11	6	5	6	0	5
Hepatitis A Virus (HAV) IgG	11	5	6	5	0	6
Hepatitis C Virus (HCV) <sup>a</sup>	11	5	6	4	1	6

Clinical Category	Number Tested	ADVIA Centaur EBV-EBNA IgG Assay Results		Comparative EBV-EBNA IgG Assay Results		
		Nonreactive	Reactive	Negative	Equivocal	Positive
Human Immunodeficiency Virus (HIV)	10	4	6	4	0	6
Herpes Simplex Virus (HSV-1) IgG <sup>b</sup>	11	5	6	4	0	7
Herpes Simplex Virus (HSV-2) IgG <sup>b</sup>	12	4	8	3	0	9
<i>Treponema pallidum</i> (Syphilis)	12	3	9	3	0	9
Varicella Zoster Virus (VZV) IgG	10	6	4	6	0	4
Measles virus IgG	13	6	7	6	0	7
Mumps virus IgG	10	4	6	4	0	6
<i>Borrelia burgdorferi</i> IgG (Lyme IgG)	11	3	8	3	0	8
Influenza virus IgG	10	2	8	2	0	8
<i>Mycoplasma pneumoniae</i> IgG <sup>a</sup>	21	14	7	14	1	6
Antinuclear antibodies (ANA)	10	9	1	9	0	1
Rheumatic Factors (RF)	12	3	9	3	0	9
Human Anti-mouse antibodies (HAMA)	12	5	7	5	0	7
Human Herpes Virus (HHV6)	14	10	4	10	0	4
Systemic Lupus Erythematosus (SLE)	10	7	3	7	0	3
Flu vaccinated patients	10	6	4	6	0	4
Elevated IgG	10	3	7	3	0	7
Epstein Barr Virus (EBV) VCA IgM	10	10	0	10	0	0
Epstein Barr Virus (EBV) EBNA IgG	10	9	1	9	0	1
<b>Total</b>	<b>330</b>	<b>168</b>	<b>162</b>	<b>165</b>	<b>2</b>	<b>163</b>

<sup>a</sup> HCV and *Mycoplasma pneumoniae* IgG: For each cross reactants, one sample produced equivocal outcome on comparative assay which was taken as discordant with ADVIA Centaur EBV-EBNA IgG assay. Possible cross-reactivity cannot be excluded based on these results. The results should be interpreted in the clinical context including signs, symptoms, and other laboratory information.

<sup>b</sup> HSV-1 IgG and HSV-2 IgG: For each cross reactants, one sample produced positive results by comparative assay. Possible cross-reactivity cannot be excluded based on these results. The results should be interpreted in the clinical context including signs, symptoms, and other laboratory information.

## 10. Stability



The onboard stability of the ADVIA Centaur EBV-EBNA IgG reagents is 28 days with a calibration interval of 28 days. The onboard stability of the ADVIA Centaur EBV-EBNA IgG Calibrators is 8 hours. The opened vial stability of the ADVIA Centaur EBV-EBNA IgG 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-EBNA IgG is substantially equivalent to the predicate device, LIAISON EBNA IgG (FDA cleared under k040120).