510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY ONLY

I Background Information:

A 510(k) Number

K233605

B Applicant

Biokit S.A.

C Proprietary and Established Names

ADVIA Centaur EBV-EBNA IgG

D Regulatory Information

Product Code(s)	Classification	Regulation Section	Panel
LSE	Class I, reserved	21 CFR 866.3235 - Epstein-Barr Virus Serological Reagents	MI - Microbiology

II Submission/Device Overview:

A Purpose for Submission:

To obtain clearance for a new device

B Measurand:

Epstein Barr Virus IgG to Nuclear Antigen (EBV-EBNA IgG)

C Type of Test:

The ADVIA Centaur EBV-EBNA IgG assay is a fully automated 2-step sandwich immunoassay using acridinium ester chemiluminescent technology.

III Intended Use/Indications for Use:

A Intended Use(s):

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.

B Indication(s) for Use:
Not applicable

C Special Conditions for Use Statement(s):
Rx - For Prescription Use Only

D Special Instrument Requirements:

The assay is intended for use on the fully automated ADVIA Centaur XP system manufactured by Siemens Healthcare Diagnostics Inc.

IV Device/System Characteristics:

A Device Description:

The ADVIA Centaur EBV-EBNA IgG assay detects IgG antibodies to the Epstein-Barr virus nuclear antigen (EBNA) in adults and pediatric serum, EDTA plasma and Lithium-Heparin Plasma. This assay is run on the fully automated ADVIA Centaur XP system. The results are intended for use in conjunction with other EBV markers as an aid in the diagnosis of Epstein-Barr virus infection, such as infectious mononucleosis.

The ADVIA Centaur EBV-EBNA IgG assay kit consists of the following components:

- 1 ADVIA Centaur EBVnaG ReadyPack containing EBVnaG Lite Reagent, Solid Phase, and Ancillary Well Reagent.
- 1 vial x 2.0 mL EBVnaG CAL low calibrator.
- 1 vial x 2.0 mL EBVnaG CAL high calibrator.
- ADVIA Centaur EBVnaG CAL calibrator assigned value cards and barcode labels.
- ADVIA Centaur EBVnaG master curve card.
- ADVIA Centaur Wash 1

The controls are available separately:

ADVIA Centaur EBV-EBNA IgG Quality Control has the following:
- Negative control
- Positive control

B Principle of Operation:

The ADVIA Centaur EBV-EBNA IgG 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.

Assay Procedure:

The system automatically performs the following steps:
1. Dispenses 20 µL of sample into a cuvette.

2. Dispenses 250 µL of Solid Phase and 90 µL of Ancillary Well Reagent into a cuvette, then incubates for 18 minutes at 37°C.

3. Performs a wash sequence using ADVIA Centaur Wash 1.

4. Dispenses 100 µL of Lite Reagent, then incubates for 18 minutes at 37°C.

5. Performs a wash sequence using ADVIA Centaur Wash 1.

6. Dispenses 300 µL of ADVIA Centaur Acid Reagent and 300 µL of ADVIA Centaur Base Reagent to initiate the chemiluminescent reaction.

7. Reports results.

Results interpretation:

The system reports ADVIA Centaur EBV-EBNA IgG assay results in Index values and as Nonreactive or Reactive:

Nonreactive: < 1.00 Index value. These samples are considered negative.
Reactive: ≥ 1.00 Index value. These samples are considered positive.

Results of this assay should always be interpreted in conjunction with the patient's medical history, clinical presentation, and other findings.

C Instrument description Information

1. Instrument Name:

   ADVIA Centaur XP System

2. Specimen Identification:

   Serum, EDTA plasma, and lithium heparin plasma are the recommended specimen types for the ADVIA Centaur EBV-EBNA IgG Assay.

3. Specimen Sampling and Handling:

   The assay needs 20 µL of sample for a single determination. The instrument performs all handling procedures automatically.

4. Calibration information:

Calibration frequency is as stated below:

- At the end of the 28-day calibration interval.
- When changing lot numbers of primary reagent packs.
- When indicated by quality control results.
- After major maintenance or service, as indicated by quality control results.

Before initiating calibration on each new lot of reagents, the assay master curve values need to be entered by scanning the master curve card.

5. Quality Control:

External positive and negative controls are available separately. According to the IFU, the controls should be used at least once during each day that samples are analyzed. In addition, quality control is performed:

- Following a valid calibration
- With use of a new lot of reagents
- When troubleshooting test results that do not match clinical conditions or symptoms

Acceptable performance is achieved when the analyte values obtained are within the expected control interval for the system.

V Substantial Equivalence Information:

A Predicate Device Name(s):

Diasorin Liaison Ebna Igg, Liaison Vca Igg, Liaison Vca Igm Assays

B Predicate 510(k) Number(s):

K040120

C Comparison with Predicate(s):

Device & Predicate Device(s):	Candidate Device K233605	Predicate Device K040120
Device Trade Name	ADVIA Centaur EBV-EBNA IgG	LIAISON EBNA IgG
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)	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-

	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.	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. *(LIAISON and LIAISON XL)
General Device Characteristic Similarities		
Measurand	IgG antibodies to the Epstein-Barr virus (EBV) nuclear antigen (EBNA)	IgG antibodies to the Epstein-Barr virus (EBV) nuclear antigen (EBNA.
Technology	Same	Chemiluminescent immunoassay (CLIA)
Antigen	Same	EBNA-1
General Device Characteristic Differences		
Sample Type	Human serum and plasma (EDTA and lithium heparin)	Human serum
Target Population	Adults and pediatrics	Adults
	As an aid in the diagnosis of Epstein-Barr virus infection, such as infectious mononucleosis	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

VI Standards/Guidance Documents Referenced:

- CLSI EP05-A3 Evaluation of Precision of Quantitative Measurement Procedures; Approved Guideline - Third Edition (Reaffirmed: September 2019).
- CLSI EP09c Measurement Procedure Comparison and Bias Estimation Using Patient Samples - 3rd Edition (2018).
- CLSI EP07 Interference Testing in Clinical Chemistry; Approved Guideline - 3rd Edition (2018).
- CLSI EP37 Supplemental Tables for Interference Testing in Clinical Chemistry - 1st Edition (2018).
- CLSI EP25-A (Replaces EP25-P) Evaluation of Stability of In Vitro Diagnostic Reagents; Approved Guideline (2009).
- CLSI EP12-Ed3 Evaluation of Qualitative, Binary Output Examination Performance (2023).
- CLSI I/LA21-A2 Clinical Evaluation of Immunoassays; Approved Guideline - 2nd Edition.

VII Performance Characteristics (if/when applicable):

A Analytical Performance:

1. Precision/Reproducibility:

a. Within-Laboratory Precision Study:

A within laboratory precision study was evaluated using 5 serum, and 5 EDTA plasma samples ranging from low negative to positive with two external controls. Samples were tested in duplicate, two runs a day for 20 days, for a total of 240 replicates per sample across all three-reagent kit lots on the ADVIA Centaur XP system. Within laboratory precision results are reported in Table 1.

Table 1. Within- Laboratory Precision results- EBV-EBNA IgG

Sample ID	Mean (Index)	N[a]	Repeatability		Between-Run		Between-Day		Between-Lot		Within-Laboratory (Total)	
			SD[b]	CV[c] (%)	SD	%CV	SD	%CV	SD	%CV	SD	%CV
Serum A	0.69	240	0.015	2.1%	0.026	3.8%	0.000	0.0%	0.006	0.9%	0.030	4.4%
Serum B	1.01	240	0.019	1.8%	0.029	2.8%	0.000	0.0%	0.092	9.0%	0.098	9.7%
Serum C	1.34	240	0.024	1.8%	0.029	2.2%	0.047	3.5%	0.167	12.5%	0.178	13.3%
Serum D	4.98	240	0.074	1.5%	0.084	1.7%	0.166	3.3%	0.326	6.5%	0.382	7.7%
Serum E	8.54	240	0.164	1.9%	0.195	2.3%	0.145	1.7%	0.187	2.2%	0.348	4.1%
Plasma A	0.71	240	0.015	2.1%	0.024	3.4%	0.005	0.7%	0.009	1.3%	0.030	4.3%
Plasma B	0.95	240	0.019	2.1%	0.028	2.9%	0.009	0.9%	0.083	8.8%	0.090	9.5%
Plasma C	1.33	240	0.025	1.9%	0.047	3.6%	0.021	1.6%	0.000	0.0%	0.058	4.3%

Plasma D	4.93	240	0.108	2.2%	0.122	2.5%	0.132	2.7%	0.121	2.5%	0.242	4.9%
Plasma E	8.76	240	0.155	1.8%	0.239	2.7%	0.116	1.3%	0.254	2.9%	0.399	4.6%
Negative Control	0.32	240	0.007	2.1%	0.007	2.1%	0.009	2.6%	0.006	1.9%	0.014	4.4%
Positive Control	3.16	240	0.051	1.6%	0.065	2.1%	0.079	2.5%	0.061	1.9%	0.130	4.1%

[a] Number of measurements.
[b] Standard deviation.
[c] Coefficient of variation.

b. Reproducibility:

Reproducibility of the ADVIA Centaur EBV-EBNA IgG assay was evaluated using 5 serum and 5 EDTA plasma samples with 2 external controls, in duplicate, twice a day, over 5 days, at three sites located in the US, using one reagent lot. Reproducibility results are reported for EBV-EBNA IgG in Table 2.

Table 2. Reproducibility results- EBV-EBNA IgG

Sample	Mean (Index)	N	Within-Run		Between-Runs		Between-Days		Between-Sites		Reproducibility	
			SD[a]	CV[b] (%)	SD	CV (%)	SD	CV (%)	SD	CV (%)	SD	CV (%)
Serum A	0.77	90	0.023	3.0	0.023	2.9	0.010	1.3	0.034	4.4	0.048	6.3
Serum B	1.07	90	0.066	6.1	0.051	4.7	0.000	0.0	0.065	6.0	0.105	9.8
Serum C	1.40	90	0.031	2.2	0.012	0.9	0.028	2.0	0.036	2.6	0.056	4.0
Serum D	4.99	90	0.103	2.1	0.119	2.4	0.077	1.6	0.255	5.1	0.310	6.2
Serum E	8.85	90	0.173	2.0	0.316	3.6	0.185	2.1	0.490	5.5	0.635	7.2
Plasma A	0.78	90	0.025	3.2	0.001	0.2	0.017	2.2	0.032	4.1	0.044	5.7
Plasma B	1.06	90	0.024	2.3	0.016	1.5	0.025	2.3	0.037	3.5	0.053	5.0
Plasma C	1.39	90	0.032	2.3	0.014	1.0	0.022	1.6	0.068	4.9	0.080	5.7
Plasma D	5.06	90	0.104	2.1	0.061	1.2	0.103	2.0	0.258	5.1	0.303	6.0
Plasma E	8.75	90	0.824	9.4	0.093	1.1	0.148	1.7	0.404	4.6	0.934	10.7
Negative Control	0.36	90	0.010	2.7	0.009	2.5	0.000	0.0	0.017	4.7	0.022	6.0
Positive Control	3.31	90	0.057	1.7	0.043	1.3	0.000	0.0	0.113	3.4	0.134	4.0

a Standard deviation of mean concentration (Index)
b Coefficient of variation
% CV= (SD/Mean)*100

2. Linearity:

Not Applicable

3. Analytical Specificity/Interference:

1. Cross reactivity:

Biokit evaluated potential cross-reactivity on the ADVIA Centaur EBV-EBNA IgG by testing at least 10 samples from individuals containing antibodies to other microorganisms or with medical conditions unrelated to EBV infections. The data showed no cross reactivity with various disease status tested except with 4 samples. Among those 4 samples, 2 samples produced equivocal results by comparator device, the LIAISON EBNA IgG. The equivocal results were interpreted as discrepant against candidate device. One sample each containing HSV-1 and HSV-2 IgG produced false nonreactive results (reactive on comparator device) on the ADVIA Centaur EBV-EBNA IgG test. The cross reactivity study results are presented in Table 3.

Table 3. Cross reactivity on the ADVIA Centaur EBV-EBNA IgG

Sample type	***Number of samples 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
Toxoplasma gondii IgG	10	5	5	5	0	5
Toxoplasma gondii 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) IgG	11	5**	6	4	1	6
Human Immunodeficiency Virus (HIV)	10	4	6	4	0	6
Herpes Simplex Virus (HSV-1) IgG	11	5*	6	4	0	7
Herpes Simplex Virus (HSV-2) IgG	12	4*	8	3	0	9
Treponema pallidum (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
Borrelia burgdorferi IgG (Lyme IgG)	11	3	8	3	0	8

Influenza virus IgG	10	2	8	2	0	8
Mycoplasma pneumoniae IgG	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 IgG	10	10	0	10	0	0
Epstein Barr Virus (EBV) VCA IgM	10	9	1	9	0	1
Total	**330**	**168**	**162**	**165**	**2**	**163**

* HSV-1 and HSV-2: For each cross reactants, one sample produced positive results by predicate device. 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.

** *Mycoplasma pneumoniae* IgG and HCV IgG: For each cross reactants, one sample gave EQV outcome on predicate device which was taken as discordant with the 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.

2. Interference study:

Biokit evaluated the potential interference of commonly found endogenous substances on the ADVIA Centaur EBV-EBNA IgG assay using negative, low positive and high positive serum, EDTA plasma, and lithium heparin plasma samples. No interference was observed at the tested interferents concentrations. The results for interference study are reported in Table 4.

Table 4. Interference study results **-**The ADVIA Centaur EBV-EBNA IgG

Interfering Substances	**Concentration**
Hemoglobin	1000 mg/dL
Conjugated Bilirubin	40 mg/dL
Unconjugated Bilirubin	40 mg/dL
Triglycerides	1500 mg/dL

Total protein (hyperproteinemia)	15 g/dL
Total protein (hypoproteinemia)	3 g/dL
Cholesterol	502 mg/dL
Biotin	3510 ng/mL

3. EBV-EBNA IgG class specificity:

Biokit performed a class specificity study to demonstrate that the ADVIA Centaur EBV-EBNA IgG assay is specific to EBV-EBNA IgG class. The results demonstrated that the ADVIA Centaur EBV-EBNA IgG assay specifically detects IgG class immunoglobulin.

4. Assay Reportable Range:

Not Applicable

5. Stability:

Sample Stability

The stability of specimens stored under different conditions was evaluated by testing a panel of natural and contrived samples (including Serum Separator Tube (SST), EDTA plasma, Lithium Heparin plasma on the ADVIA Centaur EBV-EBNA IgG assay.

The data support the following storage conditions for the serum, EDTA plasma and lithium heparin plasma on the ADVIA Centaur EBV-EBNA IgG assay. Summary of sample stability is provided in Table 5.

Table 5. Summary of serum, EDTA plasma and lithium heparin plasma stability

Stability summary of samples	**Stability Claim**
Stability Type	
Refrigerated (2 °C to 8 °C) Primary containers (on the clot or gel)	7 Days
Refrigerated (2 °C to 8 °C) in secondary containers (separated samples)	7 Days
Room Temperature (Nominal 15 °C to 30 °C) in secondary containers (separated samples)	72 hours
Frozen (Nominal -30 °C to -15 °C) (separated samples)	12 months
Freeze-thaw	5 cycles

Reagent Stability

The data support the following storage conditions for the ADVIA Centaur EBV-EBNA IgG assay reagents. Summary of reagent stability is in Table 6.

Table 6. Summary of reagent stability -The ADVIA Centaur EBV-EBNA IgG

Stability Study	Stability Claim
Reagent On-Board	28 days
Reagent Unopened Shelf Life	12 months at 2-8°C
Calibrator Unopened Shelf-Life	12 months at 2-8°C
Calibrator In-Use/Opened	60 days at 2-8°C
Calibrator at room temperature	8 hours
Controls Unopened Shelf Life	13 months at 2-8°C
Controls In-Use/Opened	60 days at 2-8°C
Controls at room temperature	8 hours

6. Sample fresh-frozen study:

   Biokit performed sample fresh-frozen study to demonstrate ADVIA Centaur EBV-EBNA IgG detects analyte equivalently in fresh vs. frozen samples. The results showed the EBV-EBNA IgG detection is similar in both fresh and frozen samples.

7. Detection Limit:

   Not Applicable

8. Assay Cut-Off:

   A study to establish the ADVIA Centaur EBV-EBNA IgG cut-off was performed using 393 intended use samples. The cut-off value was determined by performing concordance and Receiver Operator Characteristic (ROC) analysis, using predicate (LIAISON EBNA IgG) results as the standard. The estimated cut-off value for ADVIA Centaur EBV-EBNA IgG assay was established as 1.0 Index value.

9. Accuracy (Instrument):

   Not Applicable.

10. Carry-over:

The ADVIA Centaur EBV-EBNA IgG assay is not susceptible to within-assay sample carryover.

B Comparison Studies:

1. Method Comparison with Predicate Device:

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 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.

Testing was conducted at three sites in the U.S. representative of testing environments where the candidate device will be used. Table 7 presents all individual samples tested in population 1 and 2 combined with age category.

Table 7. Total study population by age

Total Study Population by Age			
Sample Age	**All individuals**		
	(N=1595)		
	N	**n/N**	**%**
Overall	1595	N/A	100.00%
Age 2-21	551	551/1595	34.55%
Age >21	1044	1044/1595	65.45%

The performance of the ADVIA Centaur EBV-EBNA IgG results in population 1(leftover remnants with adults and pediatrics) and in population 2 (selected leftover remnant with a known negative result in adults and pediatrics) for all sites combined are summarized in Tables 8 and 9.

Table 8. Population 1 performance of the ADVIA Centaur EBV-EBNA IgG in adults and pediatrics- all sites combined**.**

Population 1				
ADVIA Centaur EBV-EBNA IgG	LIAISON EBNA IgG			
	Negative	**Equivocal**	**Positive**	**Total**
Nonreactive	323	2	4	329
Reactive	23	2	1074	1099
Total	346	4	1078	1428
Performance	**NPA**=92.82% (323/348)		**PPA**= 99.44% (1074/1080)	
	95% CI: 89.61% - 95.09%		95% CI: 98.79% - 99.75%	

Table 9. Population 2 performance of the ADIVA Centaur EBV-EBNA IgG in adults and pediatrics- all sites combined**.**

Population 2				
ADVIA Centaur EBV-EBNA IgG	LIAISON EBNA IgG			
	Negative	**Equivocal**	**Positive**	**Total**
Nonreactive	164	0	0	164
Reactive	3	0	0	3
Total	167	0	0	167
Performance	**NPA**=98.2% (164/167)		N/A	
95% CI	95% CI: 94.85% - 99.39%		N/A	N/A

The ADVIA Centaur EBV-EBNA IgG results for pediatrics alone on population 1 and 2 are summarized in Table 10 and 11.

Table 10. Population 1 performance of the ADIVA Centaur EBV-EBNA IgG in Pediatrics

Population 1-pediatrics				
ADVIA Centaur EBV-EBNA IgG	**LIASON EBNA IgG**			
	Negative	**Equivocal**	**Positive**	**Total**
Nonreactive	220	2	2	224
Reactive	5	1	249	255
Total	225	3	251	479
Performance	**NPA**= 97.35% (220/226)		**PPA**= 98.42% (249/253)	
95% CI	95% CI: 94.33% - 98.78%		95% CI: 96.01%% - 99.38%	

Table 11. Population 2 performance of the ADIVA Centaur EBV-EBNA IgG in Pediatrics

Population 2-pediatric				
ADVIA Centaur EBV-EBNA IgG	LIAISON EBNA IgG			
	Negative	**Equivocal**	**Positive**	**Total**
Nonreactive	72	0	0	72
Reactive	0	0	0	0
Total	72	0	0	72
	NPA=100% (72/72)		N/A	
	95% CI: 94.94% - 100.00%			

2. Matrix Comparison:

The aim of this study was to evaluate the performance of different sample matrices with the ADVIA Centaur EBV-EBNA IgG assay. This study evaluated ninety eight (98) sets of matched samples of Serum (Serum Separator Tube) and EDTA plasma and 97 sets of matched samples of Lithium Heparin plasma with the ADVIA Centaur EBV-EBNA IgG assay on the ADVIA Centaur XP system for matrix equivalency. The samples were analyzed by regression analysis as shown in Table 12.

The data showed that the sample matrices, serum (SST), EDTA plasma and Lithium-Heparin plasma are comparable in performance.

Table 12. Regression analysis on matrix equivalence

Tube (y) vs. Serum (x)	Regression Equation	Sample Interval	N[a]	r[b]
Plasma, EDTA	y = 1.00x – 0.01 Index	0.03-19.86 Index	98	1
Plasma, lithium heparin	y = 0.98x – 0.01 Index	0.03-17.87 Index	97	0.99

a Number of samples tested.

b Correlation coefficient.

C Clinical Studies:

See section B. 1 for clinical study results.

D Clinical Cut-Off:

Not Applicable

E Expected Values/Reference Range:

The ADVIA Centaur EBV-EBNA IgG results for the study population 1 (N=1428 samples) for all sites combined by age group and sex are summarized in Table 13.

Table 13. Population 1 **(**leftover remnant study population) results by age and sex

Age Group (Years)	Sex	Reactive		Nonreactive		Total
		N[a]	%[b]	N	%	
2-21	Male	113	49.80%	114	50.20%	227
	Female	142	56.30%	110	43.70%	252
	Overall	255	53.20%	224	46.80%	479
>21	Male	290	86.60%	45	13.40%	335
	Female	554	90.20%	60	9.80%	614
	Overall	844	88.90%	105	11.10%	949
Total	Male	403	71.70%	159	28.30%	562

	Female	696	80.40%	170	19.60%	866
	Overall	1099	77.00%	329	23.00%	1428

[a] Number of samples tested.
[b] Percentages are for the numbers of reactive and nonreactive in a given row.

VIII Proposed Labeling:

The labeling supports the finding of substantial equivalence for this device.

IX Conclusion:

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