K062211

BIO-RAD

BIOPLEX 2200 EBV IgG KIT, CALIBRATORS, AND CONTROLS 510(k) SUMMARY

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

DEC - 8 2006

510(k) Number	510(k) Summary Report Date
k062211	December 7, 2006

MANUFACTURER INFORMATION

Manufacturer	
Manufacturer Address	Bio-Rad Laboratories, Inc. Clinical Systems Division 4000 Alfred Nobel Drive Hercules, CA 94547
Telephone	(510) 724-7000
Establishment Registration No.	2915274
Owner / Operator	Bio-Rad Laboratories, Inc. 4000 Alfred Nobel Drive Hercules, CA 94547
Owner / Operator No.	9929003
Official Correspondent for the BioPlex 2200 EBV IgG	
Official Correspondent Address	Bio-Rad Laboratories 6565 185th Ave NE Redmond, WA 98052
Telephone	425-881-8300
Establishment Registration No.	3022521
Owner / Operator	Bio-Rad Laboratories 6565 185th Ave NE Redmond, WA 98052
Official Correspondent	Mr. Christopher Bentsen
Telephone	(425) 498-1709
Fax	(425) 498-1651

CLASSIFICATION INFORMATION

Classification Name	Epstein Barr Virus, Other (LSE)
Common Name:	Multi-Analyte Detection System EBV IgG
Product Trade Name	BioPlex 2200 EBV IgG Panel on the BioPlex 2200 Multi-Analyte Detection System BioPlex 2200 EBV IgG Control Set BioPlex 2200 EBV IgG Calibrator Set
Device Class	Class I
Classification Panel	Microbiology
Regulation Number	866.3235

BIO-RAD

LEGALLY MARKETED EQUIVALENT (SE) DEVICES

	BioPlex2200 EBV IgG Analyte	Comparative FDA Cleared PREDICATE DEVICE	510(k) Number	Decision Date
1.	EBV NA-1	Captia EBV (EBNA-1) IgG ELISA	951549	4/29/96
2.	EBV VCA	Captia EBV VCA (P-18) IgG ELISA	980912	3/26/98
3.	EBV EA-D	Captia EBV EAD IgG ELISA	973123	7/22/98

DEVICE DESCRIPTION

The EBV IgG kit uses multiplex flow immunoassay, a methodology that greatly resembles traditional EIA, but permits simultaneous detection and identification of many antibodies in a single tube. Three (3) different populations of beads are coated with *E. coli* derived recombinant proteins, EBV NA-1 (28kD and 45kD), EBV VCA p18 (40kD), and EBV EA-D (28kD) associated with infectious mononucleosis.12-13 The BioPlex 2200 System combines an aliquot of patient sample, sample diluent, and bead reagent into a reaction vessel. The mixture is incubated at 37°C. After a wash cycle, antihuman IgG antibody, conjugated to phycoerythrin (PE), is added to the dyed beads and this mixture is incubated at 37°C. The excess conjugate is removed in another wash cycle, and the beads are re-suspended in wash buffer. The bead mixture then passes through the detector. The identity of the dyed beads is determined by the fluorescence of the dyes, and the amount of antibody captured by the antigen is determined by the fluorescence of the attached PE. Raw data is calculated in relative fluorescence intensity (RFI).

Three additional dyed beads, an Internal Standard Bead (ISB), a Serum Verification Bead (SVB) and a Reagent Blank Bead (RBB) are present in each reaction mixture to verify detector response, the addition of serum or plasma to the reaction vessel and the absence of significant non-specific binding in serum or plasma. Refer to the BioPlex 2200 System Operation Manual for more information. The instrument is calibrated using a set of seven (7) distinct calibrator vials, supplied separately by Bio-Rad Laboratories. A combination of four (4) vials representing four (4) different antibody concentrations are used for semi-quantitative calibration. The result for each of these antibodies is expressed as an antibody index (AI).

KIT COMPONENTS

EBV IgG Reagent Pack (Catalog No. 665-1250). The reagent pack contains supplies sufficient for 100 tests.

Vial	Description
Bead Set	One (1) 10 mL vial, containing 3 different populations of dyed beads coated with affinity-purified *E. coli* derived recombinant proteins to EBV NA-1 (28kD and 45kD), EBV VCA p18 (40kD), EBV EAD (28kD); an Internal Standard (ISB), a Serum Verification (SVB), and a Reagent Blank (RBB); with Glycerol and protein stabilizers (bovine) in a MOPS (3-[N-Morpholino] propanesulfonic acid) buffer. ProClin® 300 (0.3%) and sodium azide (<0.1%) as preservatives
Conjugate	One (1) 5 mL vial, containing murine monoclonal anti-human IgG/phycoerythrin conjugate and murine anti-human FXIII / phycoerythrin conjugate, in a phosphate buffer. Proclin® 300 (0.3%) and Sodium azide (0.1%) as preservatives.
Sample Diluent	One (1) 10 mL vial, containing protein stabilizers (bovine and murine) in a triethanolamine buffer. Proclin® 300 (0.3%) and Sodium azide (0.1%) as preservatives.

BIO-RAD

ADDITIONAL REQUIRED ITEMS, AVAILABLE FROM BIO-RAD

Catalog #	Description
663-1200	BioPlex 2200 EBV IgG Calibrator Set: Seven (7) 500 µL vials, containing antibodies to EBV VCA, EBV NA-1, and EBV EA-D, in a human serum matrix made from defibrinated plasma. Proclin® 300 (0.3%) as a preservative for all calibrators.
663-1230	BioPlex 2200 EBV IgG Control Set: Two (2) 1.5 mL vials of Positive Control containing antibodies to EBV NA-1, EBV VCA, and EBV EA-D, in a human serum matrix made from defibrinated plasma; and two (2) 1.5 mL vials of Negative Control in a serum matrix made from defibrinated plasma. ProClin® 300 (0.3%) as a preservative for all controls.
660-0817	BioPlex 2200 System Sheath Fluid: Two (2) 4 L bottles containing Phosphate Buffered Saline (PBS). Proclin® 300 (0.3%) and Sodium azide (0.1%) as preservatives.
660-0818	BioPlex 2200 System Wash Solution: One (1) 10 L bottle containing Phosphate Buffered Saline (PBS) and Tween 20. Proclin® 300 (0.3%) and Sodium azide (0.1%) as preservatives.
660-0000	BioPlex 2200 Instrument and Software.

INTENDED USE / INDICATIONS FOR USE

BioPlex 2200 EBV IgG Kit

The BioPlex™ 2200 EBV IgG kit is a multiplex flow immunoassay intended for the qualitative detection of IgG antibodies to three (3) separate EBV antigens; Epstein-Barr Virus Nuclear Antigen-1 (EBV NA-1), Viral Capsid Antigen (EBV VCA), and Early Antigen diffuse (EBV EA-D) in human serum. The test system can be used in conjunction with the BioPlex 2200 EBV IgM kit as an aid in the laboratory diagnosis of infectious mononucleosis (IM).

The EBV IgG kit is intended for use with the Bio-Rad BioPlex 2200 System.

Assay performance characteristics have not been established for immunocompromised or immunosuppressed patients, cord blood, neonatal specimens, or infants. Assay performance characteristics have not been established for the diagnosis of nasopharyngeal carcinoma, Burkitt's lymphoma, and other EBV-associated lymphomas.

BioPlex 2200 EBV IgG Calibrator Set

The BioPlex 2200 EBV IgG Calibrator Set is intended for the calibration of the BioPlex 2200 EBV IgG Reagent Pack.

BioPlex 2200 EBV IgG Control Set

The BioPlex 2200 EBV IgG Control Set is intended for use as an assayed quality control to monitor the overall performance of the BioPlex 2200 Instrument and BioPlex 2200 EBV IgG Reagent Pack in the clinical laboratory. The performance of the BioPlex 2200 EBV IgG Control Set has not been established with any other EBV assays.

BIO-RAD

TECHNOLOGICAL CHARACTERISTICS

The following tables summarize similarities and differences between the BioPlex 2200 EBV IgG Kit, Calibrators, and Controls and the predicate devices used in comparative studies with the BioPlex 2200 EBV IgG Kit.

A. BioPlex 2200 EBV IgG Assay: EBV NA-1

Table 1: Similarities between reagents and materials

Similarities between Components / Materials	**BioPlex 2200 EBV IgG Kit**	**Predicate EBNA-1 IgG EIA**
Reagents	Wash Buffer, Sample Diluent	Wash Buffer, Serum Diluent
Calibrator(s)	Calibrators	Calibrator
Controls	Negative Control and Multi-Analyte Positive Control (EBV VCA, EBV NA-1, and EBV EA-D)	Negative Control, Low Positive Control, and High Positive Control

Table 2: Similarities between reagents with regard to function and use

Similarities between Function and Use	**BioPlex 2200 EBV IgG Kit**	**Predicate EBNA-1 IgG EIA**
Intended Use	Qualitative detection of IgG antibodies in human serum to EBNA.	Qualitative determination of IgG antibodies in human serum to EBNA.
Matrices	Serum	Serum

Table 3: Differences between reagents and materials

Differences between Components / Materials	**BioPlex 2200 EBV IgG Kit**	**Predicate EBNA-1 IgG EIA**
Solid Phase	Bead reagent - dyed antigen coated beads	96 well microplate – antigen coated microwells
Reagents	Conjugate: Anti-human IgG / Phycoerythrin	Conjugate: Anti-Human IgG / Horse-radish Peroxidase, Substrate (TMB)
Sheath Fluid	Sheath Fluid is used to suspend the bead reagent and introduce it into the detector.	Not similar; not utilized in EIA's.

Table 4: Differences between reagents with regard to function and use

Differences between Function and Use	**BioPlex 2200 EBV IgG Kit**	**Predicate EBNA-1 IgG EIA**
Intended Use	Qualitative detection of IgG antibodies in human serum to to EBNA.	Semi-quantitative determination of IgG antibodies in human serum to EBNA.
Analyte Detection	Multi-Analyte Detection (human IgG antibodies to EBV VCA, EBV NA-1, and EBV EA-D)	Single Analyte Detection (human IgG antibodies to EBNA)

BIO-RAD

B. BioPlex 2200 EBV IgG Assay: EBV VCA

Table 5: Similarities between reagents and materials

Similarities between Components / Materials	**BioPlex 2200 EBV IgG Kit**	**Predicate EBV VCA (P-18) IgG EIA**
Reagents	Wash Buffer, Sample Diluent	Wash Buffer, Serum Diluent
Calibrator(s)	Calibrators	Cut-Off Calibrator
Controls	Negative Control and Multi-Analyte Positive Control (EBV VCA, EBV NA-1, and EBV EA-D)	Negative Control, Low Positive Control, and High Positive Control

Table 6: Similarities between reagents with regard to function and use

Similarities between Function and Use	**BioPlex 2200 EBV IgG Kit**	**Predicate EBV VCA (P-18) IgG EIA**
Intended Use	Qualitative detection of IgG antibodies in human serum to EBV Viral Capsid Antigen (VCA).	Qualitative determination of IgG antibodies in human serum to EBV Viral Capsid Antigen (VCA).
Matrices	Serum	Serum

Table 7: Differences between reagents and materials

Differences between Components / Materials	**BioPlex 2200 EBV IgG Kit**	**Predicate EBV VCA (P-18) IgG EIA**
Solid Phase	Bead reagent - dyed antigen coated beads	96 well microplate – antigen coated microwells
Reagents	Conjugate: Anti-human IgG / Phycoerythrin	Conjugate: Anti-Human IgG / Horse-radish Peroxidase, Substrate (TMB)
Sheath Fluid	Sheath Fluid is used to suspend the bead reagent and introduce it into the detector.	Not similar; not utilized in EIA's.

Table 8: Differences between reagents with regard to function and use

Differences between Function and Use	**BioPlex 2200 EBV IgG Kit**	**Predicate EBV VCA (P-18) IgG EIA**
Analyte Detection	Multi-Analyte Detection (human IgG antibodies to EBV VCA, EBV NA-1, and EBV EA-D)	Single Analyte Detection (human IgG antibodies to EBV Viral Capsid Antigen)

BIO-RAD

C. BioPlex 2200 EBV IgG Assay: EBV EA-D

Table 9: Similarities between reagents and materials

Similarities between Components / Materials	**BioPlex 2200 EBV IgG Kit**	**Predicate EBV EA-D IgG EIA**
Reagents	Wash Buffer, Sample Diluent	Wash Buffer, Serum Diluent
Calibrator(s)	Calibrators	Calibrator
Controls	Negative Control and Multi-Analyte Positive Control (EBV VCA, EBV NA-1, and EBV EA-D)	Negative Control, Low Positive Control, and High Positive Control

Table 10: Similarities between reagents with regard to function and use

Similarities between Function and Use	**BioPlex 2200 EBV IgG Kit**	**Predicate EBV EA-D IgG EIA**
Intended Use	Qualitative detection of IgG antibodies in human serum to EBV EA-D.	Qualitative determination of IgG antibodies in human serum to EBV EA-D.
Matrices	Serum	Serum

Table 11: Differences between reagents and materials

Differences between Components / Materials	**BioPlex 2200 EBV IgG Kit**	**Predicate EBV EA-D IgG EIA**
Solid Phase	Bead reagent - dyed antigen coated beads	96 well microplate – antigen coated microwells
Reagents	Conjugate: Anti-human IgG / Phycoerythrin	Conjugate: Anti-Human IgG / Horse-radish Peroxidase, Substrate (TMB)
Sheath Fluid	Sheath Fluid is used to suspend the bead reagent and introduce it into the detector.	Not similar; not utilized in EIA's.

Table 12: Differences between reagents with regard to function and use

Differences between Function and Use	**BioPlex 2200 EBV IgG Kit**	**Predicate EBV EA-D IgG EIA**
Analyte Detection	Multi-Analyte Detection (human IgG antibodies to EBV VCA, EBV NA-1, and EBV EA-D)	Single Analyte Detection (human IgG antibodies to EBV EA-D)

BIO-RAD

PERFORMANCE SUMMARY

A. Expected Values

Expected values for the EBV IgG kit are presented by age and gender in Tables 13 - 18 for serum samples from unselected hospitalized pediatric and adult patients (N=303) and patients for which an EBV test was ordered (N=620). A total of 621 serum samples from patients for which an EBV test was ordered were tested. One (1) sample from the patients for which an EBV test was ordered population was excluded due to RBB analysis error messages during BioPlex 2200 EBV IgG testing. For all analytes, results of ≤0.8 AI are negative, 0.9 and 1.0 AI are equivocal, and ≥1.1 AI are reported as positive.

Table 13: Hospitalized Patient Samples: EBV NA-1 IgG

Age	Gender	BioPlex 2200 EBV NA-1 IgG						Total
		Positive		Equivocal		Negative		
		N	%	N	%	N	%	N
< 5 years of age	F	11	41%	0	0%	16	59%	27
	M	6	30%	0	0%	14	70%	20
5-12 years of age	F	13	59%	0	0%	9	41%	22
	M	15	44%	0	0%	19	56%	34
13-20 years of age	F	28	80%	0	0%	7	20%	35
	M	10	67%	0	0%	5	33%	15
21-30 years of age	F	5	83%	0	0%	1	17%	6
	M	1	50%	0	0%	1	50%	2
31-40 years of age	F	10	100%	0	0%	0	0%	10
	M	11	100%	0	0%	0	0%	11
41-50 years of age	F	13	100%	0	0%	0	0%	13
	M	7	100%	0	0%	0	0%	7
51-60 years of age	F	22	96%	0	0%	1	4%	23
	M	18	95%	0	0%	1	5%	19
61-70 years of age	F	11	100%	0	0%	0	0%	11
	M	12	100%	0	0%	0	0%	12
71-80 years of age	F	11	100%	0	0%	0	0%	11
	M	6	100%	0	0%	0	0%	6
81-90 years of age	F	11	100%	0	0%	0	0%	11
	M	5	83%	0	0%	1	17%	6
91-100 years of age	F	0	0%	0	0%	0	0%	0
	M	2	100%	0	0%	0	0%	2
Total		228	75%	0	0%	75	25%	303

Table 14: Hospitalized Patient Samples: EBV VCA IgG

Age	Gender	BioPlex 2200 EBV VCA IgG						Total
		Positive		Equivocal		Negative		
		N	%	N	%	N	%	N
< 5 years of age	F	11	41%	0	0%	16	59%	27
	M	5	25%	0	0%	15	75%	20
5-12 years of age	F	14	64%	0	0%	8	36%	22
	M	15	44%	0	0%	19	56%	34
13-20 years of age	F	29	83%	0	0%	6	17%	35
	M	9	60%	0	0%	6	40%	15
21-30 years of age	F	6	100%	0	0%	0	0%	6
	M	1	50%	0	0%	1	50%	2
31-40 years of age	F	10	100%	0	0%	0	0%	10
	M	11	100%	0	0%	0	0%	11
41-50 years of age	F	13	100%	0	0%	0	0%	13
	M	7	100%	0	0%	0	0%	7
51-60 years of age	F	22	96%	0	0%	1	4%	23
	M	18	95%	0	0%	1	5%	19
61-70 years of age	F	10	91%	1	9%	0	0%	11
	M	11	92%	1	8%	0	0%	12
71-80 years of age	F	10	91%	1	9%	0	0%	11
	M	6	100%	0	0%	0	0%	6
81-90 years of age	F	11	100%	0	0%	0	0%	11
	M	5	83%	0	0%	1	17%	6
91-100 years of age	F	0	0%	0	0%	0	0%	0
	M	2	100%	0	0%	0	0%	2
Total		226	75%	3	1%	74	24%	303

Table 15: Hospitalized Patient Samples: EBV EA-D IgG

Age	Gender	BioPlex 2200 EA-D IgG						Total
		Positive		Equivocal		Negative		
		N	%	N	%	N	%	N
< 5 years of age	F	2	7%	0	0%	25	93%	27
	M	1	5%	1	5%	18	90%	20
5-12 years of age	F	4	18%	0	0%	18	82%	22
	M	5	15%	0	0%	29	85%	34
13-20 years of age	F	9	26%	2	6%	24	69%	35
	M	3	20%	3	20%	9	60%	15
21-30 years of age	F	2	33%	0	0%	4	67%	6
	M	1	50%	1	50%	0	0%	2
31-40 years of age	F	4	40%	2	20%	4	40%	10
	M	6	55%	0	0%	5	45%	11
41-50 years of age	F	5	38%	0	0%	8	62%	13
	M	2	29%	0	0%	5	71%	7
51-60 years of age	F	8	35%	5	22%	10	43%	23
	M	10	53%	1	5%	8	42%	19
61-70 years of age	F	3	27%	0	0%	8	73%	11
	M	5	42%	1	8%	6	50%	12
71-80 years of age	F	4	36%	2	18%	5	45%	11
	M	1	17%	0	0%	5	83%	6
81-90 years of age	F	7	64%	1	9%	3	27%	11
	M	5	83%	0	0%	1	17%	6
91-100 years of age	F	0	0%	0	0%	0	0%	0
	M	1	50%	0	0%	1	50%	2
Total		88	29%	19	6%	196	65%	303

Table 16: Samples from Patients for which an EBV Test was Ordered: EBV NA-1 IgG

Age	Gender	BioPlex 2200 EBV NA-1 IgG						Total
		Positive		Equivocal		Negative		
		N	%	N	%	N	%	N
< 5 years of age	F	6	20%	0	0%	24	80%	30
	M	9	26%	0	0%	25	74%	34
5-12 years of age	F	22	35%	0	0%	40	65%	62
	M	24	39%	0	0%	38	61%	62
13-20 years of age	F	46	59%	1	1%	31	40%	78
	M	19	49%	0	0%	20	51%	39
21-30 years of age	F	42	91%	0	0%	4	9%	46
	M	25	76%	0	0%	8	24%	33
31-40 years of age	F	50	96%	0	0%	2	4%	52
	M	22	92%	0	0%	2	8%	24
41-50 years of age	F	33	100%	0	0%	0	0%	33
	M	30	97%	0	0%	1	3%	31
51-60 years of age	F	26	96%	0	0%	1	4%	27
	M	21	81%	0	0%	5	19%	26
61-70 years of age	F	11	85%	0	0%	2	15%	13
	M	19	90%	0	0%	2	10%	21
71-80 years of age	F	2	100%	0	0%	0	0%	2
	M	3	100%	0	0%	0	0%	3
81-90 years of age	F	2	100%	0	0%	0	0%	2
	M	2	100%	0	0%	0	0%	2
91-100 years of age	F	0	0%	0	0%	0	0%	0
	M	0	0%	0	0%	0	0%	0
Total		414	67%	1	0%	205	33%	620

Table 17: Samples from Patients for which an EBV Test was Ordered: EBV VCA IgG

Age	Gender	BioPlex 2200 EBV VCA IgG						Total
		Positive		Equivocal		Negative		
		N	%	N	%	N	%	N
< 5 years of age	F	6	20%	0	0%	24	80%	30
	M	11	32%	0	0%	23	68%	34
5-12 years of age	F	21	34%	0	0%	41	66%	62
	M	28	45%	0	0%	34	55%	62
13-20 years of age	F	47	60%	0	0%	31	40%	78
	M	20	51%	0	0%	19	49%	39
21-30 years of age	F	43	93%	1	2%	2	4%	46
	M	26	79%	0	0%	7	21%	33
31-40 years of age	F	52	100%	0	0%	0	0%	52
	M	22	92%	0	0%	2	8%	24
41-50 years of age	F	32	97%	0	0%	1	3%	33
	M	31	100%	0	0%	0	0%	31
51-60 years of age	F	27	100%	0	0%	0	0%	27
	M	24	92%	0	0%	2	8%	26
61-70 years of age	F	12	92%	0	0%	1	8%	13
	M	18	86%	0	0%	3	14%	21
71-80 years of age	F	2	100%	0	0%	0	0%	2
	M	3	100%	0	0%	0	0%	3
81-90 years of age	F	2	100%	0	0%	0	0%	2
	M	1	50%	0	0%	1	50%	2
91-100 years of age	F	0	0%	0	0%	0	0%	0
	M	0	0%	0	0%	0	0%	0
Total		428	69%	1	0%	191	31%	620

Table 18: Samples from Patients for which an EBV Test was Ordered: EBV EA-D IgG

Age	Gender	BioPlex 2200 EA-D IgG						Total
		Positive		Equivocal		Negative		
		N	%	N	%	N	%	N
< 5 years of age	F	3	10%	3	10%	24	80%	30
	M	6	18%	2	6%	26	76%	34
5-12 years of age	F	7	11%	3	5%	52	84%	62
	M	6	10%	4	6%	52	84%	62
13-20 years of age	F	16	21%	8	10%	54	69%	78
	M	12	31%	2	5%	25	64%	39
21-30 years of age	F	16	35%	2	4%	28	61%	46
	M	9	27%	3	9%	21	64%	33
31-40 years of age	F	15	29%	5	10%	32	62%	52
	M	7	29%	1	4%	16	67%	24
41-50 years of age	F	10	30%	2	6%	21	64%	33
	M	4	13%	1	3%	26	84%	31
51-60 years of age	F	13	48%	3	11%	11	41%	27
	M	10	38%	1	4%	15	58%	26
61-70 years of age	F	6	46%	1	8%	6	46%	13
	M	5	24%	3	14%	13	62%	21
71-80 years of age	F	0	0%	1	50%	1	50%	2
	M	1	33%	0	0%	2	67%	3
81-90 years of age	F	0	0%	0	0%	2	100%	2
	M	1	50%	0	0%	1	50%	2
91-100 years of age	F	0	0%	0	0%	0	0%	0
	M	0	0%	0	0%	0	0%	0
Total		147	24%	45	7%	428	69%	620

BIO-RAD

B. Reproducibility Studies

A reproducibility panel, consisting of nine (9) panel members was prepared by Bio-Rad Laboratories. Two (2) of the nine (9) panel members had high levels of EBV NA-1 and EBV VCA; two (2) of the nine (9) panel members had high levels of EBV EA-D; two (2) of the nine (9) panel members had antibody levels near the cutoff for EBV NA-1 and EBV VCA; two (2) of the nine (9) panel members had antibody levels near the cutoff for EBV EA-D. All were prepared from positive patient samples. One (1) of the nine (9) panel members was negative for all three (3) analytes contained in the BioPlex 2200 EBV IgG kit. In addition, three (3) lots of the EBV IgG Control Set [1 positive control (antibody positive) and a negative control (antibody negative)] were also tested.

Reproducibility testing was performed at each of three (3) US testing facilities on a total of three (3) lots of the EBV IgG kit, three (3) lots of the EBV IgG Calibrator Set and three (3) lots of the EBV IgG Control Set. Each testing facility evaluated reproducibility using one (1) kit lot of EBV IgG with matched calibrators and controls. The panels were provided to each of the testing sites. Each of the nine (9) panel members and positive and negative controls was tested in quadruple (x4) on each day for three (3) days at each of three (3) US testing facilities using one (1) lot of EBV IgG reagent pack, one (1) lot of EBV IgG Calibrator Set and one (1) lot of EBV IgG Control Set (4 times x 3 days x 3 sites = 36 replicates per panel member and controls). The data were analyzed for intra-assay and inter-assay reproducibility according to the principles described in the Clinical Laboratory Standards Institute guidance EP5-A2, revised November 2004 and ISO/TR 22971:2205. The standard deviation (SD) and percent coefficient of variation (%CV) were calculated. Positive results can be found in Tables 19 - 21.

Table 19: Reproducibility; BioPlex 2200 EBV NA-1 IgG

EBV NA-1 IgG Panel Members	Sample N	Grand Mean AI	Within-Run		Between-Day		Between-Run		Between-Site*		Total	
			SD	%CV	SD	%CV	SD	%CV	SD	%CV	SD	%CV
High Positive 1	36	4.2	0.1	3.2	0.0	0.0	0.1	2.9	0.3	7.4	0.4	8.5
High Positive 2	36	4.3	0.1	3.4	0.1	2.5	0.1	2.8	0.3	7.5	0.4	9.0
Low Positive 1	36	1.5	0.1	4.8	0.0	0.0	0.1	5.7	0.2	11.6	0.2	13.8
Low Positive 2	36	2.1	0.1	3.2	0.0	1.1	0.1	3.7	0.2	9.4	0.2	10.7
Positive Control	36	2.9	0.1	1.9	0.0	1.1	0.1	2.4	0.5	17.2	0.5	17.5

* Between-Site variance includes between lot variance.

Table 20: Reproducibility; BioPlex 2200 EBV VCA IgG

EBV VCA IgG Panel Members	Sample N	Grand Mean AI	Within-Run		Between-Day		Between-Run		Between-Site*		Total	
			SD	%CV	SD	%CV	SD	%CV	SD	%CV	SD	%CV
High Positive 1	36	3.3	0.1	3.5	0.0	0.0	0.1	3.3	0.4	12.7	0.4	13.5
High Positive 2	36	3.2	0.1	3.4	0.0	0.0	0.1	3.7	0.2	7.3	0.3	8.9
Low Positive 1	36	1.5	0.1	5.0	0.0	0.0	0.1	5.5	0.2	16.2	0.3	17.8
Low Positive 2	36	1.3	0.1	5.8	0.0	0.0	0.1	5.0	0.1	7.6	0.1	10.8
Positive Control	36	2.3	0.1	2.8	0.0	0.0	0.1	2.7	0.1	5.6	0.2	6.9

* Between-Site variance includes between lot variance.

Table 21: Reproducibility; BioPlex 2200 EBV EA-D IgG

EBV EA-D IgG Panel Members	Sample N	Grand Mean AI	Within-Run		Between-Day		Between-Run		Between-Site*		Total	
			SD	%CV	SD	%CV	SD	%CV	SD	%CV	SD	%CV
High Positive 1	36	4.1	0.2	4.4	0.0	0.8	0.0	0.0	0.4	8.7	0.4	9.8
High Positive 2	36	4.0	0.1	3.7	0.0	0.7	0.1	3.5	0.2	6.2	0.3	8.1
Low Positive 1	36	2.3	0.2	8.8	0.1	2.8	0.0	0.0	0.1	5.7	0.2	10.9
Low Positive 2	36	2.2	0.1	4.6	0.0	0.0	0.1	3.5	0.1	4.2	0.2	7.2
Positive Control	36	3.0	0.1	3.1	0.0	0.0	0.1	2.5	0.6	18.8	0.6	19.2

* Between-Site variance includes between lot variance.

BIO-RAD

C. Precision Studies

A precision panel, consisting of six (6) panel members was prepared by Bio-Rad Laboratories. Two (2) of the six (6) panel members had high levels of the antibodies contained in the BioPlex 2200 EBV IgG kit (EBV NA-1 IgG, EBV VCA IgG, and EBV EA-D IgG) and two (2) of the six (6) panel members had antibody levels near the cutoff, both prepared from positive patient samples. Two (2) of the six (6) panel members were negative (one high negative and one low negative) for both of the analytes.

Precision testing was performed at Bio-Rad Laboratories on one lot of the EBV IgG kit, one lot of the EBV IgG Calibrator Set and one lot of the EBV IgG Control Set. Each of the six (6) panel members was tested in duplicate (x2) on two (2) runs per day for ten (10) days using one (1) lot of EBV IgG kit, one (1) lot of EBV IgG Calibrator Set and one (1) lot of EBV IgG Control Set (2 times x 2 runs x 10 days = 40 replicates per panel member). The data were analyzed for intra-assay and inter-assay precision according to the principles described in the Clinical Laboratory Standards Institute guidance EP5-A2, revised November 2004 and ISO/TR 22971:2205. The standard deviation (SD) and percent coefficient of variation (%CV) were calculated. Results can be found in Tables 22 - 24.

Table 22: Precision Results; BioPlex 2200 EBV NA-1 IgG

EBV NA-1 IgG Panel Members	Sample N*	AI Mean	Within-Run		Between-Day		Between-Run		Total	
			SD	%CV	SD	%CV	SD	%CV	SD	%CV
High Positive 1	42	4.6	0.2	4.2%	0.3	6.3%	0.3	5.9%	0.4	9.6%
High Positive 2	42	4.6	0.2	4.0%	0.2	5.4%	0.4	8.6%	0.5	10.9%
Low Positive 1	42	1.9	0.1	5.5%	0.0	0.0%	0.2	11.9%	0.2	13.1%
Low Positive 2	42	2.2	0.1	5.0%	0.0	0.0%	0.2	10.4%	0.3	11.5%
High Negative	43	0.7	0.1	7.1%	0.0	3.8%	0.1	12.1%	0.1	14.5%
Low Negative	44	0.0	0.0	0.0%	0.0	0.0%	0.0	0.0%	0.0	0.0%

**Additional samples were run.*

Table 23: Precision Results; BioPlex 2200 EBV VCA IgG

EBV VCA IgG Panel Members	Sample N*	AI Mean	Within-Run		Between-Day		Between-Run		Total	
			SD	%CV	SD	%CV	SD	%CV	SD	%CV
High Positive 1	42	3.5	0.1	3.9%	0.1	3.9%	0.2	6.8%	0.3	8.7%
High Positive 2	42	3.4	0.2	5.0%	0.1	3.7%	0.3	9.1%	0.4	11.0%
Low Positive 1	42	1.6	0.1	8.4%	0.0	2.6%	0.1	8.1%	0.2	11.9%
Low Positive 2	42	1.3	0.1	7.4%	0.1	4.1%	0.1	10.2%	0.2	13.3%
High Negative	43	0.6	0.1	10.8%	0.0	0.0%	0.1	11.4%	0.1	15.7%
Low Negative	44	0.2	0.0	16.3%	0.0	6.8%	0.0	5.1%	0.0	18.4%

**Additional samples were run.*

Table 24: Precision Results; BioPlex 2200 EBV EA-D IgG

EBV EA-D IgG Panel Members	Sample N*	AI Mean	Within-Run		Between-Day		Between-Run		Total	
			SD	%CV	SD	%CV	SD	%CV	SD	%CV
High Positive 1	42	4.3	0.2	4.6%	0.0	0.0%	0.3	6.9%	0.4	8.3%
High Positive 2	42	4.2	0.3	6.0%	0.3	6.3%	0.3	7.2%	0.5	11.2%
Low Positive 1	42	2.3	0.2	10.3%	0.1	4.5%	0.2	9.8%	0.3	14.9%
Low Positive 2	42	2.3	0.2	7.0%	0.2	6.8%	0.2	9.1%	0.3	13.4%
High Negative	43	0.7	0.1	13.4%	0.0	0.0%	0.1	12.9%	0.1	18.6%
Low Negative	44	0.2	0.1	29.8%	0.0	5.3%	0.0	0.0%	0.1	30.3%

**Additional samples were run.*

D. Comparative Testing

Typical Antibody Response Characterization

The following table demonstrates a generally accepted algorithm for classifying patients into an EBV status via serologic profiles. EBV status can be applied to any patient based on results of standard tests. In acute IM, both EBV IgM and EBV IgG antibodies to viral capsid antigen (VCA) rise rapidly. EBV VCA IgM antibody disappears over about four weeks. Heterophile antibody, which is of the IgM class, appears only during acute infection and fades rapidly over about four weeks. EBV EA-D IgG antibody shows a transient rise during acute infection, and becomes undetectable after 3 - 6 months. EBV NA-1 IgG antibody usually appears 3 months after initial infection and typically remains for life, as well as EBV VCA IgG.

Table 25: Serological Status

EBV Serological Status	EBV NA-1 IgG	EBV VCA IgG	EBV EA-D IgG	EBV VCA IgM	Heterophile Antibody
Primary Acute	Neg (-)	Pos (+)	Pos (+)	Pos (+)	Neg (-)
	Neg (-)	Neg (-)	Pos (+)	Pos (+)	Pos (+)
	Neg (-)	Pos (+)	Neg (-)	Pos (+)	Pos (+)
	Neg (-)	Neg (-)	Neg (-)	Pos (+)	Pos (+)
	Neg (-)	Neg (-)	Neg (-)	Pos (+)	Neg (-)
	Neg (-)	Neg (-)	Pos (+)	Pos (+)	Neg (-)
	Neg (-)	Pos (+)	Pos (+)	Pos (+)	Pos (+)
	Neg (-)	Pos (+)	Pos (+)	Neg (-)	Pos (+)
Late Acute	Neg (-)	Pos (+)	Neg (-)	Pos (+)	Neg (-)
	Pos (+)	Pos (+)	Pos (+)	Pos (+)	Pos (+)
	Pos (+)	Pos (+)	Pos (+)	Pos (+)	Neg (-)
	Pos (+)	Pos (+)	Neg (-)	Pos (+)	Pos (+)
	Pos (+)	Pos (+)	Pos (+)	Neg (-)	Neg (-)
	Pos (+)	Pos (+)	Neg (-)	Pos (+)	Neg (-)
Recovering	Neg (-)	Pos (+)	Pos (+)	Neg (-)	Neg (-)
Previous Infection	Neg (-)	Pos (+)	Neg (-)	Neg (-)	Neg (-)
	Pos (+)	Pos (+)	Neg (-)	Neg (-)	Neg (-)
Susceptible	Neg (-)	Neg (-)	Neg (-)	Neg (-)	Neg (-)

Notes: For the purposes of serological characterization, equivocal results were considered negative. Any serological pattern not identified in Table 25 should be considered inconclusive.

Comparison of BioPlex 2200 EBV IgG kit and Microplate EIA

Performance of the BioPlex 2200 EBV IgG kit was tested against corresponding commercially available microplate EIAs. A total of 621 banked serum samples from patients for which an EBV test was ordered were tested at 3 U.S. clinical testing sites. The BioPlex 2200 EBV IgG kit was run in conjunction with the BioPlex 2200 EBV IgM kit to allow for a complete antibody response profile. The characterization by antibody response was not compared with clinical data regarding presence, absence or status of disease. Two (2) samples were excluded due to RBB analysis error messages during BioPlex 2200 EBV IgM testing. One (1) sample was excluded due to RBB analysis error messages during BioPlex 2200 EBV IgG testing. Using Table 25 as a guideline, results were analyzed by BioPlex 2200 EBV IgG analytes and corresponding EBV IgG reference assays according to serological characterization based on reference assay results. For the purpose of percent agreement calculations, BioPlex 2200 EBV IgG equivocal results were assigned to the opposite clinical interpretation than that of the corresponding reference assay result. Likewise, the reference IgG assay equivocal results were assigned to the opposite clinical interpretation than that of the corresponding BioPlex 2200 EBV IgG result. Results from all sites are shown and summarized in Tables 26 - 31.

Table 26: BioPlex 2200 EBV NA-1 IgG vs. EIA: Comparison by Serological Pattern Characterization

EBV Serological Status	Reference EBV NA-1 IgG Interpretation									Total
	Positive			Equivocal			Negative			
	BioPlex 2200 EBV NA-1 IgG			BioPlex 2200 EBV NA-1 IgG			BioPlex 2200 EBV NA-1 IgG			
	Pos	Eqv	Neg	Pos	Eqv	Neg	Pos	Eqv	Neg	
	N	N	N	N	N	N	N	N	N	N
Primary Acute	0	0	0	0	0	0	0	0	31	31
Late Acute	104	0	4	0	0	0	0	0	2	110
Recovering	0	0	0	0	0	0	0	0	4	4
Previous Infection	285	1	4	0	0	0	4	0	11	305
Susceptible	0	0	0	0	0	1	1	0	125	127
Inconclusive	20	0	9	0	0	0	0	0	12	41
Overall	409	1	17	0	0	1	5	0	185	618

Table 27: BioPlex 2200 EBV NA-1 IgG vs. EIA: Percent Agreement & Confidence Intervals by Serological Pattern Characterization

EBV Serological Status	Positive Agreement		95% CI	Negative Agreement		95% CI
Primary Acute	(0/0)	N/A*	N/A*	(31/31)	100%	89.0 -100%
Late Acute	(104/108)	96.3%	90.9 - 98.6%	(2/2)	100%	34.2 - 100%
Recovering	(0/0)	N/A*	N/A*	(4/4)	100%	51.0 -100%
Previous Infection	(285/290)	98.3%	96.0 - 99.3%	(11/15)	73.3%	48.0 - 98.1%
Susceptible	(0/1)	0.0%	N/A*	(125/126)	99.2%	95.6 - 99.9%
Inconclusive	(20/29)	69.0%	50.8 - 82.7%	(12/12)	100%	75.8 - 100%
Overall	(409/428)	95.6%	93.2 - 97.1%	(185/190)	97.4%	94.0 - 98.9%

**In cases where agreement resulted in a numerator of zero (0), 95% confidence interval could not be calculated; in cases where agreement resulted in (0/0) samples, percent agreement and 95% confidence interval could not be calculated.*

Table 28: BioPlex 2200 EBV VCA IgG vs. EIA: Comparison by Serological Pattern Characterization

EBV Serological Status	Reference EBV VCA IgG Interpretation									Total
	Positive			Equivocal			Negative			
	BioPlex 2200 EBV VCA IgG			BioPlex 2200 EBV VCA IgG			BioPlex 2200 EBV VCA IgG			
	Pos	Eqv	Neg	Pos	Eqv	Neg	Pos	Eqv	Neg	
	N	N	N	N	N	N	N	N	N	N
Primary Acute	4	0	3	0	0	1	0	0	23	31
Late Acute	106	0	4	0	0	0	0	0	0	110
Recovering	4	0	0	0	0	0	0	0	0	4
Previous Infection	296	1	8	0	0	0	0	0	0	305
Susceptible	0	0	0	0	0	0	0	0	127	127
Inconclusive	16	0	0	0	0	0	1	0	24	41
Overall	426	1	15	0	0	1	1	0	174	618

Table 29: BioPlex 2200 EBV VCA IgG vs. EIA: Percent Agreement & Confidence Intervals by Serological Pattern Characterization

EBV Serological Status	Positive Agreement		95% CI	Negative Agreement		95% CI
Primary Acute	(4/8)	50.0%	21.5 - 78.5%	(23/23)	100%	85.7 - 100%
Late Acute	(106/110)	96.4%	91.0 - 98.6%	(0/0)	N/A*	NA*
Recovering	(4/4)	100%	51.0 - 100%	(0/0)	N/A*	NA*
Previous Infection	(296/305)	97.0%	94.5 - 98.4%	(0/0)	N/A*	NA*
Susceptible	(0/0)	N/A*	NA*	(127/127)	100%	97.1 - 100%
Inconclusive	(16/16)	100%	80.6 - 100%	(24/25)	96.0%	80.5 - 99.3%
Overall	(426/443)	96.2%	93.9 - 97.6%	(174/175)	99.4%	96.8 - 99.9%

**In cases where agreement resulted in (0/0) samples, percent agreement and 95% confidence interval could not be calculated.*

Table 30: BioPlex 2200 EBV EA-D IgG vs. EIA: Comparison by Serological Pattern Characterization

EBV Serological Status	Reference EBV EA-D IgG Interpretation									Total
	Positive			Equivocal			Negative			
	BioPlex 2200 EBV EA-D IgG			BioPlex 2200 EBV EA-D IgG			BioPlex 2200 EBV EA-D IgG			
	Pos	Eqv	Neg	Pos	Eqv	Neg	Pos	Eqv	Neg	
	N	N	N	N	N	N	N	N	N	N
Primary Acute	18	1	2	0	0	0	2	1	7	31
Late Acute	72	1	3	4	0	0	6	3	21	110
Recovering	4	0	0	0	0	0	0	0	0	4
Previous Infection	0	0	0	5	3	3	23	22	249	305
Susceptible	0	0	0	0	1	1	0	9	116	127
Inconclusive	10	2	1	0	0	0	2	2	24	41
Overall	104	4	6	9	4	4	33	37	417	618

Table 31: BioPlex 2200 EBV EA-D IgG vs. EIA: Percent Agreement & Confidence Intervals by Serological Pattern Characterization

EBV Serological Status	Positive Agreement		95% CI	Negative Agreement		95% CI
Primary Acute	(18/21)	85.7%	65.4 - 95.0%	(7/10)	70.0%	39.7 - 89.2%
Late Acute	(72/76)	94.7%	87.2 - 97.9%	(21/34)	61.8%	45.0 - 76.1%
Recovering	(4/4)	100%	51.0 - 100%	(0/0)	N/A*	N/A*
Previous Infection	(0/3)	0.0%	N/A*	(249/299)	83.3%	78.6 - 87.1%
Susceptible	(0/1)	0.0%	N/A*	(116/125)	92.8%	86.9 - 96.2%
Inconclusive	(10/13)	76.9%	49.7 - 91.8%	(24/28)	85.7%	68.5 - 94.3%
Overall	(104/118)	88.1%	81.1 - 92.8%	(417/496)	84.1%	80.6 - 87.0%

**In cases where agreement resulted in a numerator of zero (0), 95% confidence interval could not be calculated; in cases where agreement resulted in (0/0) samples, percent agreement and 95% confidence interval could not be calculated.*

Comparison of Characterization EBV Serological Status

Using Table 25 as a guideline, samples characterized into serological status associated with EBV disease, using the commercially available microplate EIA and agglutination tests, were compared with characterizations using BioPlex 2200 EBV IgG and IgM kits. The EBV IgG kit was run in conjunction with the EBV IgM kit to allow for a complete antibody response profile. The characterization by antibody response was not compared with clinical data regarding presence, absence or status of disease. Results from 618 serum samples tested at 3 U.S. clinical testing sites are shown in Table 32.

Table 32: Comparison of EBV Serological Status

	EBV Serological status	BioPlex 2200 EBV IgG & IgM Profile								
		Primary Acute	Late Acute	Recovering	Previous Infection	Susceptible	Inconclusive	Total	% Serological Agreement	95% Confidence Interval
Commercially Available Assays	Primary Acute	30	0	0	0	0	1	31	96.8%	83.8 - 99.4%
	Late Acute	5	90	1	13	0	1	110	81.8%	73.6 - 87.9%
	Recovering	1	0	3	0	0	0	4	75.0%	30.0 - 95.4%
	Previous Infection	0	31	2	263	4	5	305	86.2%	81.9 - 89.7%
	Susceptible	4	0	0	0	122	1	127	96.1%	91.1 - 98.3%
	Inconclusive	6	10	0	7	11	7	41	17.1%	8.5 - 31.3%
	Overall	46	131	6	283	137	15	618	83.3%	80.2 - 86.1%

Note: Calculations are performed for unshaded areas only.

Comparison of Acute and Non-acute EBV Serological Status

The results obtained from the summarized information provided in Table 32 were further classified into two groups; Acute Infection and Non-Acute Infection. Acute Infection includes Primary Acute and Late Acute. Non-Acute Infection includes samples characterized as Susceptible, Recovering and Previous Infection as defined in Table 25. Inconclusive includes any samples whose patterns of antibody reactivity are not consistent with any category listed in Table 25. Results are summarized in Table 33.

Table 33: Acute vs. Non-acute

EBV Serological status		BioPlex 2200 EBV IgG & IgM Profile					
		Acute	Non-Acute	Inconclusive	Total	% Serological Agreement	95% Confidence Interval
Commercially Available Assays	Acute	125	14	2	141	88.7%	82.4 - 92.9%
	Non-Acute	36	394	6	436	90.4%	87.2 - 92.8%
	Inconclusive	16	18	7	41	17.1%	8.5 - 31.3%
	Overall	177	426	15	618	85.1%	82.1 – 87.7%

Note: Calculations are performed for unshaded areas only.

E. Cross-Reactivity

A cross-reactivity study was performed to determine if samples from various disease states and other potentially interfering factors interfere with test results when tested with the BioPlex 2200 EBV IgG kit. A panel of ten (10) specimens* positive for each cross reactant were evaluated for possible cross reactivity with the BioPlex 2200 EBV IgG kit for each of the three EBV IgG antibody assays. Due to the high prevalence of EBV IgG antibodies in the normal population, the test specimens were also evaluated on corresponding commercially available microplate EIAs. Most of the samples evaluated were high positive for each disease state. The majority of all samples that did elicit a positive result were also confirmed positive by the corresponding commercially available microplate EIA, indicating reactivity to EBV IgG antibodies rather than cross reactivity with a potentially interfering factor. Results can be found in Table 34.

**Due to limited availability of samples, only four E. coli specimens were evaluated.*

Table 34: Cross Reactivity

Cross Reactives	N	Method	BioPlex 2200 EBV IgG		
			EBV NA-1 IgG	EBV VCA IgG	EBV EA-D IgG
ANA	10	BioPlex 2200	9	10	7
		EIA	9	10	7
		Discrepants	0	0	0
Rheumatoid Factor	10	BioPlex 2200	10	10	1
		EIA	10	10	1*
		Discrepants	0	0	0
Toxo IgG	10	BioPlex 2200	9	9	2
		EIA	9	9*	2*
		Discrepants	0	0	0
Rubella IgG	10	BioPlex 2200	10	10	2
		EIA	10	10	1*
		Discrepants	0	0	1
CMV IgG	10	BioPlex 2200	10	10	2
		EIA	10	10	2**
		Discrepants	0	0	1
VZV IgG	10	BioPlex 2200	8	8	1
		EIA	9	8	1
		Discrepants	1	0	0
HSV-1 IgG	10	BioPlex 2200	10	10	2
		EIA	10	10	3
		Discrepants	0	0	1
HSV-2 IgG	10	BioPlex 2200	10	10	3
		EIA	10	10	4
		Discrepants	0	0	1
HIV	10	BioPlex 2200	10	9	1
		EIA	10	10	2**
		Discrepants	0	1	1
E. coli	4	BioPlex 2200	4	4	0
		EIA	4	4	0*
		Discrepants	0	0	0
Pregnant women	10	BioPlex 2200	9	9	3
		EIA	9	10	3*
		Discrepants	0	1	0

*One Equivocal Sample; **Two Equivocal Samples

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Mr. David Bhend
Regulatory Affairs Associate
Bio-Rad Laboratories, Inc.
Diagnostics Group
6565 185th Ave, N.E.
Redmond, WA 98052

DEC - 8 2006

Re: k062211
Trade/Device Name: BioPlex 2200 EBV IgG Panel on the BioPlex 2200 Multi-Analyte Detection System
BioPlex 2200 EBV IgG Control Set
BioPlex 2200 EBV IgG Calibrator Set
Regulation Number: 21 CFR 866.3235
Regulation Name: Epstein-Barr virus serological reagents
Regulatory Class: Class I
Product Code: LSE
Dated: November 13, 2006
Received: November 14, 2006

Dear Mr. Bhend:

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. 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.

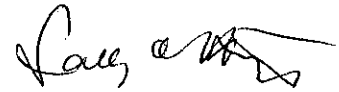
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish 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 Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0484. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150, or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,



Sally A. Hojvat, M.Sc., Ph.D.
Director
Division of Microbiology Devices
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) Number: k062211

Device Name: BioPlex 2200 EBV IgG Kit on the BioPlex 2200 Multi-Analyte Detection System
BioPlex 2200 EBV IgG Control Set
BioPlex 2200 EBV IgG Calibrator Set

Indications for Use:

BioPlex 2200 EBV IgG Kit
The BioPlex™ 2200 EBV IgG kit is a multiplex flow immunoassay intended for the qualitative detection of IgG antibodies to three (3) separate EBV antigens; Epstein-Barr Virus Nuclear Antigen-1 (EBV NA-1), Viral Capsid Antigen (EBV VCA), and Early Antigen diffuse (EBV EA-D) in human serum. The test system can be used in conjunction with the BioPlex 2200 EBV IgM kit as an aid in the laboratory diagnosis of infectious mononucleosis (IM).

The EBV IgG kit is intended for use with the Bio-Rad BioPlex 2200 System.

Assay performance characteristics have not been established for immunocompromised or immunosuppressed patients, cord blood, neonatal specimens, or infants. Assay performance characteristics have not been established for the diagnosis of nasopharyngeal carcinoma, Burkitt's lymphoma, and other EBV-associated lymphomas.

BioPlex 2200 EBV IgG Calibrator Set
The BioPlex 2200 EBV IgG Calibrator Set is intended for the calibration of the BioPlex 2200 EBV IgG Reagent Pack.

BioPlex 2200 EBV IgG Control Set
The BioPlex 2200 EBV IgG Control Set is intended for use as an assayed quality control to monitor the overall performance of the BioPlex 2200 Instrument and BioPlex 2200 EBV IgG Reagent Pack in the clinical laboratory. The performance of the BioPlex 2200 EBV IgG Control Set has not been established with any other EBV assays.

Prescription Use: ___X___ AND/OR Over-The-Counter Use: _____
(Per 21 CFR 801.109) (Optional Format 1-2-96)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division Sign-Off

Office of In Vitro Diagnostic
Device Evaluation and Safety

510(k) K062211