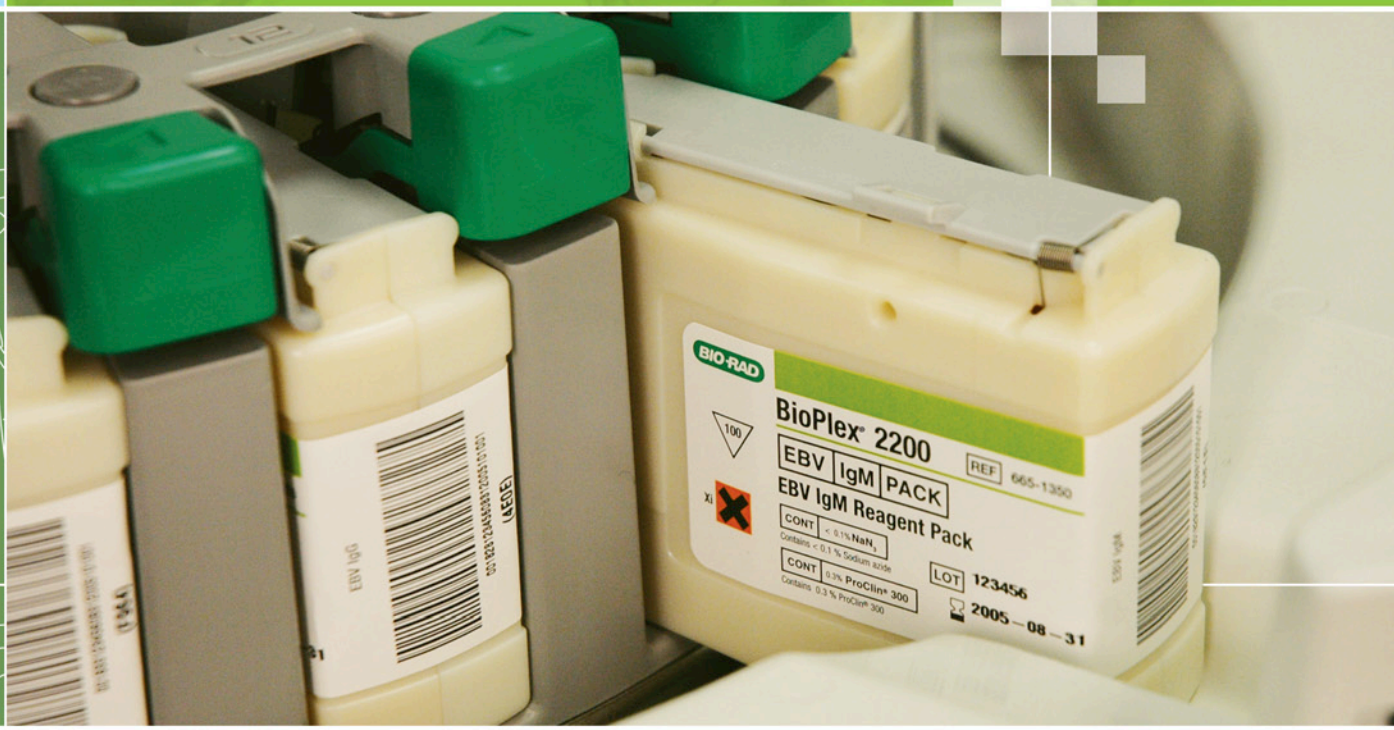
BioPlex® 2200 EBV IgG and IgM Kits

The first and only fully-automated, multiplexed solution for Epstein-Barr Virus Antibody testing

BIO-RAD



Like no other

The BioPlex® 2200 EBV IgG and IgM kits simultaneously detect the five most clinically relevant antibodies

By detecting the five antibodies of highest clinical significance, including heterophile antibody, the BioPlex® 2200 EBV IgG and IgM kits provide laboratories with more relevant information for improved diagnosis of Infectious Mononucleosis and for management and follow-up of EBV infected patients.

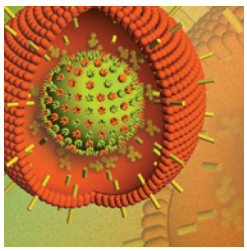
BioPlex® 2200 EBV IgG kit:

- EBV VCA IgG
- EBV NA-1 IgG
- EBV EA-D IgG

BioPlex® 2200 EBV IgM kit:

- EBV VCA IgM
- Heterophile IgM

Quality



Automated EIA-like Heterophile Antibody Detection

All the benefits of full automation and EIA technology:

- Minimizes subjectivity linked to non-EIA methods
- Improves reproducibility

Enhanced Acute Infection Diagnosis

Combining heterophile with VCA IgM enhances the clinical diagnosis of acute Infectious Mononucleosis.

Excellent Precision

Heterogeneous assay format and approximately 200 readings per analyte dramatically enhance assay precision.

Antibodies of Clinical Utility

By associating the five essential EBV antibodies, BioPlex® 2200 EBV IgG and IgM kits provide complete information to precisely determine EBV patient status.

Confidence

Full Automation

From primary tube to final result, Bioplex® 2200 is the only fully-automated, multiplexed EBV testing system:

- Minimizes sample and reagent handling errors
- Standardizes the assay procedure for improved performance

Internal Quality Controls

For every sample processed, three internal quality controls are also processed, dramatically improving confidence in the results:

- Serum Verification Bead (SVB) confirms presence of serum
- Internal Standard Bead (ISB) standardizes detector performance
- Reagent Blank Bead (RBB) identifies sample problems associated with non-specific binding

Efficiency

High Throughput Capability

Up to 190 IgG and IgM results per hour for improved workflow and reduced turnaround time.

Optimal Ease-of-Use

All reagents, calibrators and controls are ready-to-use and all the procedure steps are fully-automated. No operator intervention is required from sample loading to result release, significantly reducing hands-on-time, labor costs and cost-per-patient result.

eFlex™ Software

The system features a powerful package of software tools that provides optimum flexibility:

- “Add-on” of new test orders from previously run patient samples
- Creation of custom EBV panels
- Bi-directional LIS connectivity

Comparison Using Serological Status

618 results were obtained using commercially available ELISA microplate and agglutination tests and the BioPlex® 2200 EBV IgG and IgM kits. Samples were then assigned a serological status for both methods using a generally accepted EBV Serology Interpretation table. The BioPlex® 2200 EBV IgG and IgM kits show excellent correlation with commercially available assays for each disease status, with fewer samples categorized as Inconclusive.

	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%

	EBV Serological Status	BioPlex® 2200 EBV IgG & IgM Profile					
		Primary 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%

Reproducibility

Following CLSI EP5-A guidelines, the BioPlex® 2200 EBV IgG and IgM kits positive controls were run at 3 clinical sites for 3 days, 4 times a day, for a total of 36 replicates. The BioPlex® 2200 EBV IgG and IgM kits offer excellent reproducibility for both Within-Run and Between-Run calculations. Outstanding reproducibility can be attributed to: a) full automation, b) magnetic bead, heterogenous format of the assay and c) approximately 200 measurements per analyte (up to 4 times other multiplex methods).

Positive Control	Sample N	Grand Mean AI	Within-Run		Between-Run	
			SD	%CV	SD	%CV
EBV VCA IgG	36	2.3	0.1	2.8%	0.1	2.7%
EBV NA-1 IgG	36	2.9	0.1	1.9%	0.1	2.4%
EBV EA-D IgG	36	3.0	0.1	3.1%	0.1	2.5%

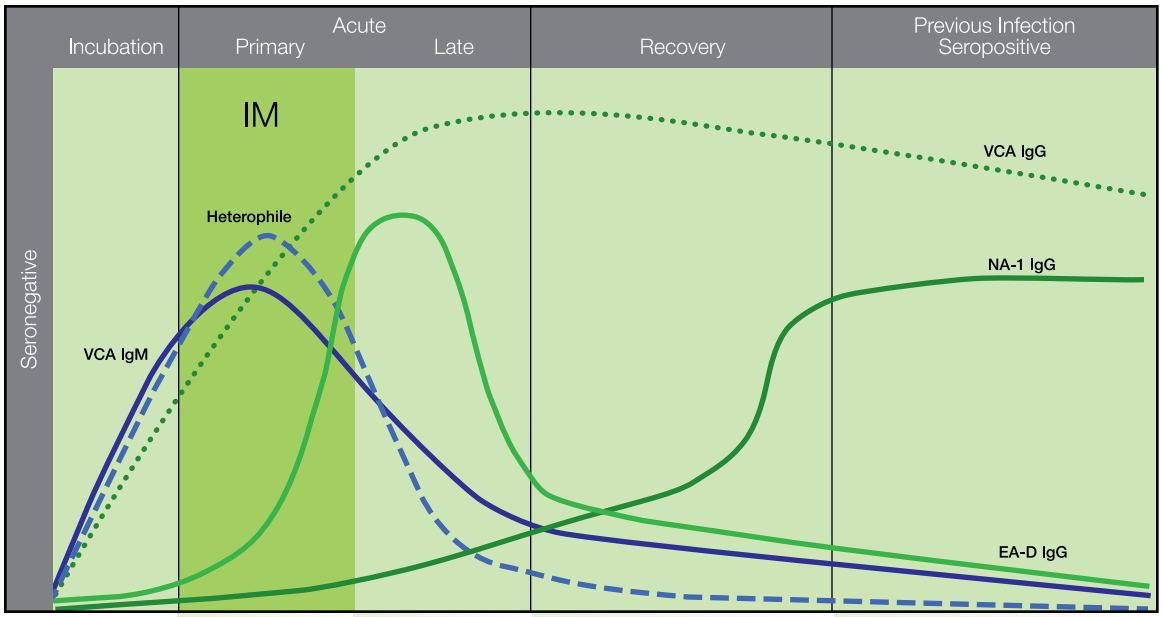
Positive Control	Sample N	Grand Mean AI	Within-Run		Between-Run	
			SD	%CV	SD	%CV
EBV VCA IgM	36	2.0	0.1	5.5%	0.1	3.0%
Heterophile IgM	36	2.5	0.1	5.3%	0.0	0.0%

EBV Infection Diagnosis

Infectious Mononucleosis (IM) diagnosis is typically based on the detection of Heterophile antibodies and antibodies against specific Epstein-Barr Virus antigens:

- Viral Capsid Antigen: EBV VCA IgG and EBV VCA IgM
- Nuclear Antigen: EBV NA-1 IgG
- Early Antigen: EBV EA-D IgG

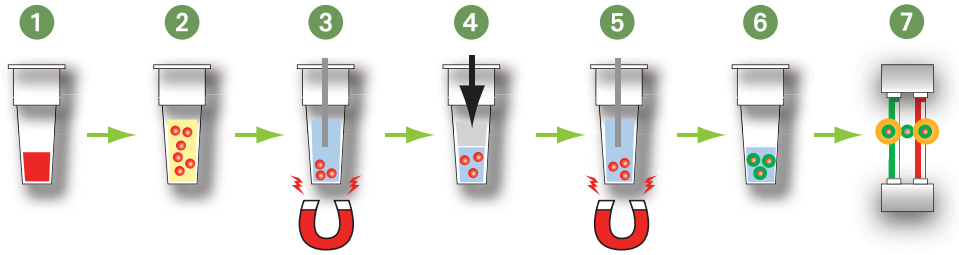
Combining Heterophile IgM and VCA IgM detection enhances the detection of acute IM. Determining the complete Patient EBV Serological profile is essential to define the stage of the infection.



	Acute		Recovery	Previous Infection Seropositive
Heterophile	+/– Normally present in acute IM	+/–	– Typically absent during recovery phase	–
VCA IgM	+/– Normally present in acute IM	+/–	– Generally absent during recovery phase	– A rise can be seen in reactivation phase
VCA IgG	+/– Normally present in acute IM	+	+ Generally present during recovery phase	+ Normally persists for lifetime
EA-D IgG	+/– Frequently present in acute IM	+/–	–/+ Generally absent during recovery phase	– A rise can be seen in reactivation phase
NA-1 IgG	– Rarely present in acute IM	+/–	+/– Typically rise during recovery phase	+/– Normally persists for lifetime

Adapted from: J.M. Seigneurin, Apport du laboratoire dans l'infection à virus Epstein-Barr Laboratory diagnosis of Epstein-Barr virus infections. Immuno-analyse & Biologie Spécialisée 1 (2002) 33–39.

EBV IgG and IgM Assays Procedure



1. Patient sample (5 µL) automatically added to Reaction Vessel
2. Sample diluent & beads (dilution 1:60) added and incubated at 37°C
3. Wash step
4. Conjugate added and incubated at 37°C
5. Wash step
6. Bead resuspended in wash buffer
7. Flow-based, dual laser detection

EBV IgG and IgM Reagent Packs
Each contains all the necessary reagents (sample diluent, beads and conjugate) to process 100 samples per pack and up to 3 (IgG) and 2 (IgM) results per sample.

EBV IgG and IgM Calibrator Sets
The EBV IgG and IgM kit calibrators are multiplexed and ready-to-use.

EBV IgG and IgM Control Sets
The EBV IgG and IgM kit controls are multiplexed and ready-to-use.

Ordering Information

Catalog No.	Description
BioPlex® 2200 EBV IgG Panel	
665-1250	EBV IgG Panel ..... 1 pack
663-1200	EBV IgG Calibrator Set..... 1 set
663-1230	EBV IgG Control Set..... 1 set
BioPlex® 2200 EBV IgM Panel	
665-1350	EBV IgM Panel .....1 pack
663-1300	EBV IgM Calibrator Set.....1 set
663-1330	EBV IgM Control Set.....1 set

BioPlex® 2200 System and Bulk Reagents

660-0000	BioPlex® 2200 System.....1 system
660-0800	Sample Racks (30 per box).....1 box
660-0801	Sample Tray.....1 tray
660-0817	Instrument Sheath Fluid (2 per box) .....1 box
660-0818	Instrument Wash Buffer.....1 box
660-2003	Reaction Vessels (1000 per bag)..... 1 bag
666-0001	Instrument Detector Calibration Pack .....1 pack
666-0002	Instrument Detector Clean Pack.....1 pack
666-0003	Instrument Probe Cleaning Solution (4 per box).....1 box

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Clinical Diagnostics Group

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