

# EVALUATION OF BIO-RAD RDT EBV ASSAYS (VCA IGG, EBNA IGG AND VCA IGM)

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## INTRODUCTION

Epstein Barr Virus (EBV) is a member of the herpes virus family that causes acute mononucleosis and is a candidate causative agent for many human cancers. Acute infection with EBV can vary widely with regard to the severity and presentation of illness, ranging from an asymptomatic infection to a serious, life-threatening version of mononucleosis. The variety of symptoms and overlap with other viral infections underscore the importance of laboratory testing in the diagnosis of acute EBV-related disease. After initial infection, the virus becomes latent and can reactivate later in life causing various diseases. Serological markers for EBV infection are the most commonly diagnostic tools used for this purpose. Several analytical methods (IFA, EIA, immunoblot, etc.) have been developed for each major serological marker (VCA IgG and IgM; EBNA IgG; EA IgG; heterophilic antibodies). Bio-Rad RDT EBV IgG and IgM Assays are rapid immunofiltration tests for the detection of antibodies (VCA IgG, EBNA IgG and VCA IgM) against EBV. These qualitative tests allow individual analysis. The entire procedure (from the preparation of sample to the result) lasts 5-10 minutes and the reading is visual. **In this study, we evaluated the performance (sensitivity and specificity) of Bio-Rad RDT EBV Assays by comparison with those of ImmunoWELL™ (GenBio) and Vidas® (Bio-Mérieux) EBV assays.**

## MATERIAL AND METHODS

The sera were tested with the three methods described above. When results were discordant, serological status was defined following the 2 out of 3 statistical method. Based on results obtained with the three tests and according to criteria described by Klutts<sup>1</sup>, the samples analysed (n=197) showed the following profiles: EBV naive (n=48), primary acute (n=47), recovery (n=13) and past infection (n=89).



Two examples of results. Left (Sample #1084986) profile of an acute infection: positive reaction only for VCA IgG (bottom band of EBV-G) and VCA IgM (bottom band of EBV-M). Top bands correspond to positive controls. Right (sample # 982181) profile of a past infection : positive reaction only for VCA IgG (bottom band of EBV-G) and EBNA IgG (central band of EBV-G).

**Table 1: Correlation between sample classification based on Bio-Rad RDT assay and serological status**

		Serological status			
		Naive	Acute	Recovery	Past
Bio-Rad RDT EBV Assays	Naive	47	1	2	
	Acute		45	1	
	Recovery	1	1	10	3
	Past				86

**Table 2: list of discrepant results**

Serological status				Bio-Rad RDT EBV Assay			Remarks	
VCA IgG	EBNA IgG	VCA IgM	Interpretation	Interpretation	VCA IgG	EBNA IgG		VCA IgM
neg	neg	POS	Acute	Naive	neg	neg	neg	Heterophile antibodies positive
POS	neg	neg	Recovery	Naive	neg	neg	neg	VCA IgG of the other tests weak positive
POS	neg	neg	Recovery	Naive	neg	neg	neg	VCA IgG of the other tests weak positive
POS	POS	POS	Recovery	Acute	POS	neg	POS	Heterophile antibodies positive
POS	POS	Neg	Past	Recovery	POS	POS	POS	
POS	POS	Neg	Past	Recovery	POS	neg	neg	
POS	POS	neg	Past	Recovery	POS	POS	POS	
POS	neg	POS	Acute	Recovery	POS	neg	neg	Heterophile antibodies positive
neg	neg	neg	Naive	Recovery	POS	POS	POS	Possible non-specific reactions

**Table 3: Relative sensitivity and specificity**

	VCA IgG	EBNA IgG	VCA IgM
<b>Sensitivity</b>	95.6%	97.8%	96.2%
<b>Specificity</b>	90.3%	99.1%	97.2%

## RESULTS

The serological profiles based on Bio-Rad RDT EBV Assays of 188 out of 197 sera were similar of the serological status defined following the rules described in "Material and Methods" section (table 1).

Results of 9 sera were discordant for at least one marker (table 2), leading to a different interpretation compared to that of the defined serological status. In all these cases (naive, acute and recovery) the clinical attitude is to request a second sample 2-3 weeks later for a final serological interpretation, which generally help to define the exact serological status.

On the basis of the chosen criteria, the relative sensitivities of the tests performed with Bio-Rad RDT EBV Assay were of 95.6% (VCA IgG), 97.8% (EBNA IgG) and 96.2% (VCA IgM) (table 3). The relative specificities were of 90.3% (VCA IgG), 99.1% (EBNA IgG) and 97.2% (VCA IgM). These results are in accordance with sensitivities and specificities claimed by the manufacturer.

## CONCLUSION

- Relative sensitivity and specificity of Bio-Rad RDT EBV Assays were consistent with the data claimed by the manufacturer and in agreement with the diagnostic requirements.
- no discordances with significant clinical relevance were present.
- The test is simple to perform, fast and easy to read.

**In our study, the Bio-Rad RDT EBV Assays showed good performances and we can conclude that they are a reliable alternative for laboratories.**

## REFERENCES

1. Klutts JS et al. Evidence-based approach for interpretation of Epstein-Barr virus serological patterns. *J Clin Microbiol.* 2009; 47:3204-10.