

# EVALUATION OF THE DIESSE CHORUS EBV ASSAYS

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## INTRODUCTION

Serology testing for Epstein - Barr virus (EBV) is commonly requested in diagnostic pathology. Currently, most laboratories in Australia perform EBV serology using microtitre enzyme immunoassays (EIA) as few automated options are available. In our laboratory, samples are batched and tested twice weekly, resulting in less than desired turnaround times. The Diesse Chorus (DC) (distributed by Laboratory Diagnostics) and the diaSorin Liaison (distributed by Immuno) are currently the only two automated assays available in Australia. Testing samples by the Chorus can be performed daily as minimum calibration and controls are required due to the use of disposable, separate, self-contained testing devices.

## METHODS

A total of 224 serum samples obtained from individuals acutely infected with EBV (n=84) and blood donors with no clinical history (n=140) were characterised using the Trinity Biotech (TB) EIA, Oxoid Infectious Mononucleosis heterophile antibody assay (IM), and/or blood film and the Euroimmune Western Blot assay. These samples were used to estimate the sensitivity and specificity of the Chorus EBV Viral Capsid Antigen (VCA) IgM, VCA IgG and EB Nuclear Antigen (EBNA) IgG assays. A further 79 samples known to contain potentially cross-reacting antibodies were also tested in the Chorus EBV VCA IgM assay to determine that assay's level of cross-reactivity. Intra-run precision was estimated by testing patient serum known to have low reactivity (S/Co <5) repeatedly in each Chorus EBV assay. A commercially-available EBV multimarker quality control sample was also tested with each test run and the inter-run precision calculated.

## RESULTS

Four of the 79 potentially cross-reacting samples, (ASOT, Cardiolipin, Rubella and Mycoplasma IgM reactive samples) were found to be reactive by Chorus EBV IgM (S/Co range 2.8-5.8). These samples were negative by the TB VCA IgM EIA assay. No cross-reaction was found with the 6 Parvovirus IgM reactive samples tested.

### Diesse Chorus EBV Assays Sensitivity and Specificity

EBV Antibody	Samples tested	Sensitivity% & (95%CI)	Samples tested	Specificity% & (95%CI)
VCA IgM	84	94-95 (86-98)*	140	97-99 (92-100)*
VCA IgG	97	98-99 (92-100)*	34	100 (97-100)
EBNA IgG	92	96 (89-99)	36	94 (80-99)

\*A range is reported when equivocal results are treated as positive and negative

### Diesse Chorus EBV Assays Precision Measured as a Coefficient of Variation (CV%)

EBV Antibody	Low level patient samples tested	% CV (intra-run)	Commercial QC Samples tested	% CV (inter-run)
VCA IgM	30	17.4	*25	37
VCA IgG	22	5.9	27	21
EBNA IgG	22	6.6	27	14.3

\* Results tested as >20 but included in the statistics as 21

### Diesse Chorus Equivocal results

EBV Antibody	Samples tested	% Initially equivocal	% Repeatedly equivocal
VCA IgM	303	2.3	0.67
VCA IgG	224	8.9	6.25
EBNA IgG	224	0.89	0.45

### EBV VCA IgG % negative and equivocal samples from acutely infected patient panel

Assay	% Negative	% Equivocal
TB	73	1.2
DC	44	10.7



## DISCUSSION

The Diesse Chorus EBV assays use partially purified EBV antigens in a sandwich EIA. The instrument has a built-in computer and printer resulting in a small footprint. It is user-friendly and has both manual entry and barcode reader facilities. Maintenance and calibration is minimal requiring only daily priming/rinsing and a sanitation rinse periodically. Up to 30 mixed EBV assays can be performed within 75 minutes.

The Chorus failed to detect 4 EBV VCA IgM positives but classified an additional 5 equivocal and 2 negative IgM samples by TB as detected. Based on the IM/film results and negative EBNA IgG (by Chorus) it is likely these samples were indeed from patients with acute EBV infections.

One sample from the blood donors tested positive for EBV IgM by both the Chorus (S/Co = 8.2) and TB and was EBNA IgG negative (by Chorus) suggesting an acute infection.

The chorus EBV VCA IgG appears to be more sensitive than the TB EBV VCA IgG as 6 of the blood donor samples that tested negative by TB were found to be positive by Chorus and confirmed by the Euroimmune Western Blot assay. In addition, a higher proportion of VCA IgG were detected by Chorus in the acute infection panel compared to TB EBV VCA IgG.

## CONCLUSION

The results of the study show that the Chorus EBV assays have a high sensitivity and specificity which is acceptable for routine diagnostic EBV testing and screening when the limitations of each assay are taken into account. The Chorus offers the advantages of automation and improved turnaround times.

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