International Medical Products N.V. / S.A.

EVALUATION OF THE CHORUS EPSTEIN-BARR VIRUS VCA IgG, VCA IgM & EBNA IgG COMPARED TO A VCA IgG & VCA IgM IMMUNOFLUORESCENCE METHOD

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Background:

In order to answer the request for evaluations of the CHORUS EBV kits in the Belgian market, a short evaluation of the EBV VCA IgM and EBV VCA IgG CHORUS tests has been performed in comparison with a VCA IgG & VCA IgM immunofluorescence technique, at Cliniques de l'Europe site Saint Michel Bruxelles. In addition, the CHORUS EBNA IgG has been tested on the same samples.

Methods:

Thirty-seven samples have been tested on both techniques, whereas one sample could only be evaluated on both IgM tests (insufficient volume).
The first samples had been evaluated previously on the immunofluorescence technique from the company Focus diagnostics

Results:

	sample	Immunofluorescence VCA IgG titer	VCA IgM IF Interpretation	CHORUS VCA IgG Ratio	Interpretation	VCA IgM Interpretation	EBNA IgG Ratio	Interpretation
	1	1/512	Doubtful	5	POS	NEG	3,7	POS
	2	1/128	POS	0,8	Doubtful	POS	0	NEG
	3	1/256	Doubtful	3,1	POS	NEG	4,9	POS
Lupus patient	4	"non specific" reaction		6,7	POS	NEG	5,1	POS
	5	1/256	POS	1,3	POS	POS	0	NEG
	6	1/512	POS	6,4	POS	NEG	4,6	POS
	7	1/256	POS	2,1	POS	NEG	0,9	Doubtful
	8		POS			POS		
	9	1/512	Doubtful	4,6	POS	NEG	5,2	POS
	10	1/512	NEG	4,8	POS	NEG	6,8	POS
	11	1/512	Doubtful	7,9	POS	NEG	7,4	POS
	12	1/512	Doubtful	3	POS	NEG	7,5	POS
mixup sample	13	1/256	POS	0,4	NEG	NEG	0,2	NEG
	14	1/512	Doubtful	4,5	POS	NEG	>20	POS
	15	1/512	NEG	6,5	POS	NEG	2,8	POS
	16	1/512	NEG	5	POS	NEG	7,5	POS
	17	1/512	NEG	5	POS	NEG	6,7	POS
	18	1/512	NEG	7,3	POS	NEG	>20	POS
	19	NEG	NEG	0,4	NEG	NEG	0	NEG
	20	1/128	NEG	3	POS	NEG	5,5	POS
	21	NEG	NEG	0,1	NEG	NEG	0,1	NEG
	22	1/128	NEG	1,4	POS	NEG	5,6	POS
	23	NEG	NEG	0,4	NEG	NEG	0,1	NEG
	24	1/512	NEG	6,6	POS	NEG	6	POS
	25	1/128	NEG	2,4	POS	NEG	7,3	POS
	26	1/64	NEG	1,9	POS	NEG	5,3	POS
	27	1/512	NEG	5,6	POS	NEG	6,2	POS
	28	1/128	NEG	2,9	POS	NEG	2,8	POS
	29	1/256	NEG	6,2	POS	NEG	6,2	POS
	30	1/1024	POS	2,6	POS	POS	0	NEG
	31	1/256	NEG	6,4	POS	NEG	6,1	POS
	32	1/512	NEG	4,2	POS	NEG	5,3	POS
	33	1/128	NEG	4,4	POS	NEG	0,5	NEG
	34	1/256	NEG	6,6	POS	NEG	5,9	POS
	35	1/512	NEG	6,2	POS	NEG	6,7	POS
	36	1/256	NEG	3,3	POS	NEG	4,4	POS
	37	1/256	NEG	2,3	POS	NEG	6,2	POS

Interpretation guidelines of CHORUS EBV kits:
The Chorus instrument expresses the result as an INDEX (ratio between the OD value of the test sample and that of the Calibrator).
- POSITIVE: when the ratio is > 1.2
- DOUBTFUL: when the ratio is between 0.8 and 1.2
- NEGATIVE: when the ratio is < 0.8

Table 1: overview results

			IMMUNOFLUORESCENCE					CHORUS		
			VCA IgG (n=36)		VCA IgM (n=37)			EBNA IgG (n=36)		
			POS	NEG	POS	NEG	Doubtful	POS	NEG	Doubtful
CHORUS	VCA IgG (n=36)	POS	31					27	3	1
		NEG	1*	3					4	
		Doubtful	1						1	
	VCA IgM (n=37)	POS			4				3	
		NEG			4*,**	23	6	27	5	1
	EBNA IgG (n=36)	POS	27		2	19	6			
		NEG	5*	3	4	4				
		Doubtful	1		1					

* one sample resulted positive with IF VCA IgG & IGM, while CHORUS VCA IgG, VCA IgM & EBNA IgG results were negative. Most probably, the discrepancy is due to a mix-up of samples.
** 1 sample from a SLE patient, gave non-specific reactivity on the IF VCA IgM

Results:

Based on the IF VCA IgM positive results, 5 samples (not sample 4, 8 & 13) could have a primo EBV infection (acute mononucleosis).Performing an EBNA IgG, heterophilic antibody test and follow-up sample would make the diagnosis.
From those 5 samples, 3 samples resulted positive on the CHORUS VCA IgM with a negative EBNA IgG, which indicates an acute mononucleosis.
The other 2 IF VCA IgM samples, resulted negative on the CHORUS VCA IgM with positive or doubtful EBNA IgG, indicating a past infection.

Considering the subjective aspect of immunofluorescence, a more objective method as the CHORUS, brings a solution. Nevertheless, real borderline samples will yield doubtful results with both methods when taking into account normal test variations.
In case of IF VCA IgG negative or IF VCA IgM positive results, the determination of EBNA IgG could give a better diagnosis. Nevertheless, in 3 cases (samples 2, 5 & 30) testing a follow-up sample is still necessary to confirm the recovery of a primo-EBV infection.
One sample (n° 33) with a negative EBNA IgG and positive VCA IgG, should also be retested on a follow-up sample in order to confirm a "late EBNA IgG" or " EBNA IgG non-responder".

Conclusion:

The Chorus automate is a user friendly and easy to use multi-parametric processor, providing quick and objective results compared to the immunofluorescence technique, without reagent loss and therefore a very good alternative for daily automatisation of EBV tests.