

EVALUATION OF AUTOMATED CHEMILUMINESCENT IMMUNOASSAYS FOR ANTI-CITOMEGALOVIRUS IGM AND IGG ANTIBODIES DETECTION.

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Background and purpose

We evaluated automated Access CMV IgG and CMV IgM chemiluminescent assays, on two UniCel DxI 800 platforms linked to a Power Processor, in comparison with VIDAS CMV IgG and IgM assays (ELFA technique) used as current methods for CMV screening in our laboratory.

Experimental approaches

The Access CMV IgG assay is a chemiluminescent sequential two-step immunoenzymatic (“sandwich”) assay. Paramagnetic particles are coated with inactivated CMV antigen and anti-human IgG monoclonal antibody is conjugate with alkaline phosphatase. The Access CMV IgM assay is a chemiluminescent two-step enzyme immunoassay using an indirect technique. Paramagnetic particles are coated with inactivated CMV antigen and sheep polyclonal anti-human IgM antibody is conjugate with alkaline phosphatase. CMV IgG and CMV IgM concordance studies were performed on 242 serum samples from routine. Results were interpreted according to manufacturer instructions, as reported in table 1.

Table 1.		UniCel DxI		VIDAS	
CMV-IgG	Non reactive	≤11	AU/mL	≤4	AU/mL
	Equivocal	11 - 15	AU/mL	4 - 6	AU/mL
	Reactive	≥15	AU/mL	≥6	AU/mL
CMV-IgM	Non reactive	<0.8	S/CO	<0.7	Index
	Equivocal	≥0.8<1.0	S/CO	≥0.7<0.9	Index
	Reactive	≥1.0	S/CO	≥0.9	Index

Results

CMV IgG concordance analysis result was 99% (Table 2), with 3 discordant cases weakly positive on VIDAS and negative or equivocal on DxI 800 (Table 3).

CMV IgM concordance was 91%, with 20 cases (Table 4) to discuss as follow and described in Table 5: 9 samples (Group 1) VIDAS negative were DxI 800 positive, with values always from 1 to 1.8 S/CO (cut-off = 1 S/CO); 6 samples (Group 2) VIDAS negative were equivocal on DxI 800 (grey-zone 0.8-1 S/CO); other 2 discordant cases (Group 3) were equivocal on VIDAS and weakly positive on DxI 800: both showed high avidity IgG (1 Parvovirus positive, 1 gammopathy); last 3 cases (Group 4) were VIDAS positive or equivocal and DxI 800 negative. These 3 cases had high avidity IgG and no specific CMV IgG increase during follow-up (EBV patients).

		VIDAS/CMV IgG		
		N	E	R
DxI 800/Access CMV IgG	N	46	0	2
	E	0	1	1
	R	0	0	192
		concordance: 99%		

Table 2: CMV IgG concordance table.

		VIDAS/CMV IgM		
		N	E	R
DxI 800/Access CMV IgM	N	200	1	2
	E	6	2	0
	R	9	2	20
		concordance: 91%		

Table 4: CMV IgM concordance table.

Sample	VIDAS Results	DxI 800 Results
1	9	7,8
2	12	5
3	17,9	12

Table 3: CMV IgG discrepant results.

	Sample	VIDAS Result	DxI 800 Result
Group 1	1	0,35	1,66
	2	0,37	1,77
	3	0,25	1,58
	4	0,39	1,80
	5	0,59	1,37
	6	0,53	1,17
	7	0,62	1,80
	8	0,35	1,21
	9	0,59	1,28
Group 2	10	0,14	0,91
	11	0,28	0,91
	12	0,54	0,97
	13	0,10	0,87
	14	0,30	0,98
	15	0,57	0,86
Group 3	16	0,77	1,42
	17	0,73	1,33
Group 4	18	0,80	0,74
	19	0,89	0,28
	20	0,74	0,15

Table 5: CMV IgM discrepant results.

Conclusion

Access CMV IgG and CMV IgM assays exhibited good correlation with our routine method, which is also the reference one. UniCel DxI 800 did not miss any positive CMV IgM case compared with VIDAS. Access CMV IgG and CMV IgM assays are sensitive for screening and adequate for CMV infection diagnosis. These assays, together with Toxo and Rubeo tests already available on board, as HIV, HCV and HBV panels, are easy to perform in total automation on UniCel DxI 800 and due to this platform high throughput, can also be suitable for high test volume laboratories.