VALIDATION OF A NEW AUTOMATED CHEMILUMINESCENT ASSAY FOR SERODIAGNOSIS OF HUMAN PARVOVIRUS B19 INFECTION

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OBJECTIVES

The aim of this study was to assess the performance characteristics of the new Biotrin Parvovirus B19 IgM and IgG assays, adapted by Biotrin International to be fully automated on LIAISON® instrument (DiaSorin). We have compared this assay with the Biotrin International 4th generation enzyme immunoassay(1) performed on the Eti-max analyser (DiaSorin).

(1) *Comparative evaluation of two commercial enzyme immunoassays for serodiagnosis of human parvovirus B19 infection*, M. Enders et al., Journal of Virological Methods 146 (2007) 409-413 .

MATERIALS

A total of 357 sera from routine daily practice were evaluated.

GROUP 1

137 sera for IgM and 160 sera for IgG were tested to evaluate the correlation between the two methods.

GROUP 2

Specificity of IgM LIAISON® Biotrin assay was assessed in detail by testing 60 serum samples with presence of potentially interfering antibodies

5	*Toxoplasma* IgM	5	*Borrelia* IgM
10	EBV IgM	5	HSV IgM
5	HCV	10	Anti- nuclear Ab
10	CMV IgM	10	Rheumatoïd Factor

METHODS

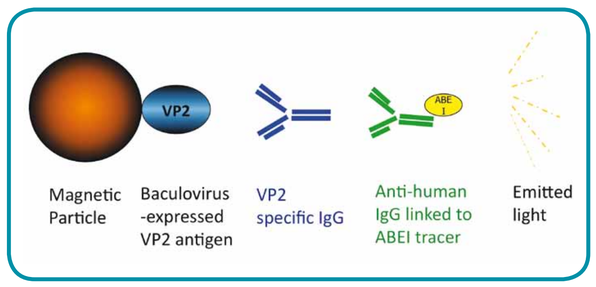
Parvovirus B19 IgM and IgG EIA 4th generation Biotrin International and Biotrin LIAISON® methods are based on a sandwich antibody technique (IgM is also a μ-capture). The reagent used for both method is a VP2 recombinant antigen recombinant from parvovirus B19 (derived from baculovirus).

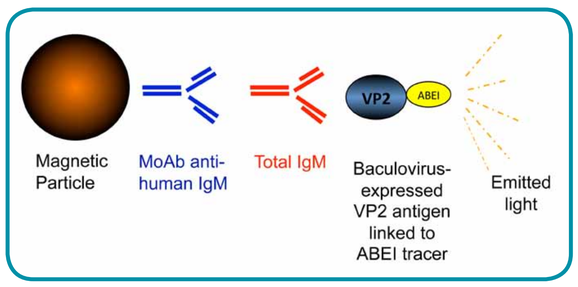
Parvovirus IgM and IgG	Technique	Automate
4th generation Biotrin (a)	ELISA	Eti-max 3000
LIAISON® Biotrin (a)	CLIA	LIAISON

LIAISON®

Eti-max 3000®

Interpretation of the results (a)	Positive	Equivocal	Negative	(Units)
Parvovirus IgM	< 0,9	0,9 - 1,1	> 1,1	(Index)
Parvovirus IgG	< 0,9	0,9 - 1,1	> 1,1	(Index)



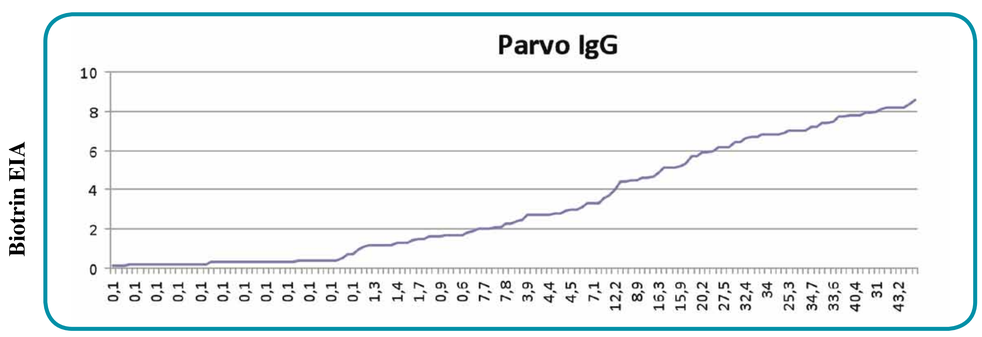


Discordant results were re-tested a second or third time, and if still not resolved, were determined by indirect immunofluorescence (IFI) testing.

RESULTS

IgM LIAISON® Biotrin				
IgM EIA Biotrin	POS	EQV	NEG	
POS	30	1	0	32
EQV	1	1	2	4
NEG	1(a)	0	100	101
	32	2	102	136

IgG LIAISON® Biotrin				
IgG EIA Biotrin	POS	EQV	NEG	
POS	103	0	7(b)	110
EQV	0	0	1	1
NEG	0	0	48	48
	103	0	56	159



Discordant IgM result:

N	EIA	LIAISON	IFI	*Conclusion*
1	NEG	POS(a)	NEG	NEG

(a) *low positive result*

Discordant IgG results:

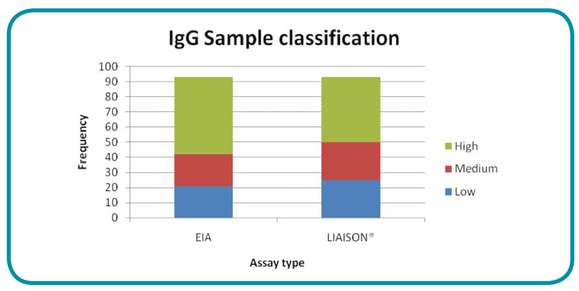
N	EIA	LIAISON	IFI	*Conclusion*
6	POS(b)	NEG	NEG	NEG
1	POS(b)	NEG	POS	POS

(b) *low positive results*

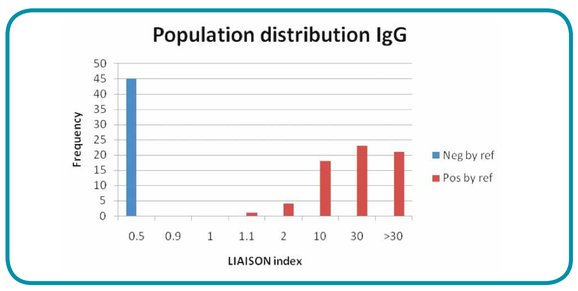
Correlation between Biotrin EIA and LIAISON Biotrin assays:

Parvovirus IgM	
positive	96,8%
negative	99%
TOTAL	**99,2%**

Parvovirus IgG	
positive	93,6%
negative	87,3%
TOTAL	**95,6%**



The ability to semi-quantitate through the distribution of low, medium, and high index samples, as with the Biotrin EIA IgG assay has been maintained with the LIAISON® kits.



There was observed a clear distribution of the positive and negative populations in terms of index results.

- We have **not highlighted significant cross- reactions** between parvovirus IgM and the other antibodies tested.
- **Intra-assay** and **inter-assay imprecision** were **less than 10% CV** for both positive IgM and IgG samples.
- We have confirmed through paired sample testing that there is **no cross-contamination effect** for either the IgG or IgM assays

CONCLUSION

The LIAISON® Parvovirus B19 IgM and IgG assays appear to be a valid alternative for the detection of parvovirus B19 antibodies. Moreover, LIAISON® parvovirus IgG assay shows better specificity than Biotrin 4th generation EIA assay for results close to the equivocal range. These assays combine robust analytical and clinical performance with the advantage of fully automated, random access instrument system (continuous loading of samples, improvement of turn-around time, ease of use, tracking of internal controls on GLIMS).

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