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).


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

Materials and 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 methods is a VP2 recombinant antigen recombinant from parvovirus B19 (derived from baculovirus).

Parvovirus IgM and IgG

4th Generation

Biotrin (®)

LIAISON® Biotrin (®)

Technique
ELISA
CLIA

Automate
Eti-max 3000
LIAISON®

Interpretation of the results (®)

Positive
Equivocal
Negative

(Index)

Parvovirus IgM
< 0.9
0.9 - 1.1
> 1.1

Parvovirus IgG
< 0.9
0.9 - 1.1
> 1.1

RESULTS

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

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%

METHODS

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

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.

Discordant IgM results:

Discordant IgG results:

(a) low positive result
(b) low positive result

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%

We have not highlighted significant cross- reactions between parovirus IgM and the other antibodies tested.

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).